

**Report of the Advisory Committee
to the Director, National Institutes of Health**

**Review of the
National Institutes of Health
Research Training Programs**

**June 1, 1990
Bethesda, Maryland**

**Proceedings of the 61st Meeting
of the Advisory Committee to the Director,
National Institutes of Health**

**Review of the
National Institutes of Health
Research Training Programs**

Prepared by the Office of Science Policy and Legislation

FOR ADMINISTRATIVE USE

U.S. Department of Health and Human Services

Public Health Service
National Institutes of Health

June 1, 1990

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Executive Summary

The Advisory Committee to the Director (ACD), National Institutes of Health (NIH), joined by representatives of the National Advisory Councils and Boards of the NIH Institutes, met on June 1 to consider the report and recommendations of the NIH Task Forces for the Review of the NIH Biomedical Research Training Programs and also to consider a new NIH effort to initiate a 5-year research strategy at NIH. During the opening remarks of the meeting, Advisory Committee members and Council representatives received a status report on activities undertaken and planned as a result of the 60th ACD meeting, held on January 26, 1990. The Acting Director, NIH, Dr. William Raub, reported on the status of efforts to ensure continued progress in the administration of medical rehabilitation research at NIH. The Deputy Director for Intramural Research, NIH, Dr. Joseph Rall, then reported on activities related to strengthening the scientific review procedures of the NIH intramural research program.

In keeping with the principal purpose of the meeting—consideration of the recommendations of the NIH Task Forces for the Review of the NIH Biomedical Research Training Programs—representatives from the National Academy of Sciences (NAS), the Association of American Medical Colleges (AAMC), and the Association of American Universities (AAU) spoke on the broad context of biomedical research training. Task force members then summarized the deliberations, conclusions, and recommendations of the task forces on Physician Scientist Training, Training in Clinical and Community-Based Study Designs and Methodology, and Predoctoral and Postdoctoral Training of Nonphysician Scientists. Following that, Dr. George Galasso, Acting Director for Extramural Affairs, NIH, reported on activities undertaken to implement task force recommendations. After the presentations, Committee members and Council representatives discussed the recommendations of the three task forces. Advisory Committee member Mr. Rodney Nichols introduced the deliberations emphasizing the need for evaluation of and greater accountability regarding goal setting for NIH training programs as a whole.

During their deliberations, Advisory Committee members and Council representatives agreed with most of the task forces' recommendations and suggested some refinements. Committee members urged judicious wording of the recommendations concerning a minimum of 2 years of training for professional doctorate appointees, modification of the payback requirement, and implementation of 3-year K-series awards to ensure flexibility. While Committee members also agreed on the recommendation to support training of M.D.'s in epidemiology, biostatistics, and related topics, they believed the recommendation required further internal attention regarding training of others. The Committee did not reach a consensus, however, on the recommendation for a two-tier cost of education allowance as a mechanism to limit tuition payments and encouraged NIH staff to continue

to work toward a fair and balanced mechanism for addressing this problem. Throughout their deliberations, Committee members demonstrated great concern about the negative impact the current fiscal climate was having on NIH training activities and on the biomedical research enterprise as a whole.

The second portion of the meeting focused on a new NIH effort to initiate a 5-year research strategy. The rationale, objectives, and plans for this initiative were presented by Dr. Raub and the Associate Director for Science Policy and Legislation, NIH, Dr. Jay Moskowitz. Council representatives and Committee members reacted favorably to the planned initiative and suggested that it should be promoted both to increase its visibility outside the health research field and to provide information to the general public, Congress, and the executive branch.

Opening Remarks

Dr. Raub reported on the status of activities related to physical medicine and rehabilitation research. The Panel on Physical Medicine and Rehabilitation Research, composed of a group of consultants to the ACD, met in November 1989 to assess the current administration of medical rehabilitation research at NIH and to develop recommendations for ensuring continued progress in this area. After reviewing the panel's report at its January 26 meeting, the ACD concluded that

- An immediate effort to create a Center for Rehabilitation Sciences at NIH, as recommended by some within the medical rehabilitation research community, is premature;
- Activities related to medical rehabilitation research at NIH should be strengthened and this research area needs to capitalize on the strength of the several relevant NIH components and their ongoing and planned programs; and
- The Office of the Director, NIH, should initially assume an active coordinating role in developing a comprehensive plan for this area of research and in creating a transgovernmental entity to coordinate medical rehabilitation research within the Federal sector.

As a result of the panel's report and the related ACD conclusions, a task force on medical rehabilitation research made up of 100 national experts in the field of medical rehabilitation has been established. The task force is organized into panels addressing five areas of science: neurophysiological dysfunction, musculoskeletal disorders, cancer rehabilitation, geriatrics, and developmental issues in rehabilitation. It also includes four cross-study panels addressing basic and clinical research training; biomechanics; ergonomics and engineering; information resources; and assessment, epidemiology, and biostatistics.

The task force has the mandate both to identify the current state of knowledge in the area, research program goals, and major scientific and clinical opportunities, and to develop recommendations, priorities, and strategies for pursuing program goals and opportunities within the various NIH components. In reporting to the Senate Appropriations Committee in February 1990, Dr. Raub indicated that the work of this group of outside experts will result in a major policy initiative to ensure the strengthening of medical rehabilitation research supported by NIH. After its 2-day meeting at the end of June 1990, the task force will prepare a report on its deliberations.

The Deputy Director for Intramural Research, NIH, reported on activities related to strengthening the scientific review procedures of the NIH intramural research program. Committees of scientists have reviewed intramural research at NIH since 1956. A report issued in December 1988 on an independent study by NAS and the Institute of Medicine expressed concerns about the accountability and independence of the scientific review procedures of this research program. The Panel on Strengthening the Scientific Review Procedures of the NIH Intramural Research Program, composed of a group of consultants to the ACD, met in September 1989 to examine all aspects of current intramural research at NIH and to develop recommendations for strengthening its review procedures. After reviewing the panel's report at their January 26 meeting, Advisory Committee members and Council representatives indicated their agreement with the panel's 16 recommendations. These recommendations focused on evaluation of the scientific and administrative performance of the scientific directors; nomination, terms of office, and feedback of scientific counselors; and review functions and processes.

A modified policy for the review of intramural research, to be issued soon, has adopted all of the panel's suggestions with the recommended ACD revisions. This policy will apply to all NIH Institutes, as well as to intramural research of the National Institute of Mental Health and the National Institute on Alcohol Abuse and Alcoholism, which takes place on the NIH campus and is integrated into the NIH intramural program.

Among the recommendations that have been incorporated into the modified policy is the extension of the terms of the scientific counselors from 4 to 5 years. This change will increase the counselors' familiarity with the operation of the intramural program and enhance the continuity of the review process. The chair of each Board of Scientific Counselors will nominate members to the Board in collaboration with the Scientific Director of the Institutes; currently, the Scientific Director has primary responsibility for these nominations. The Scientific Directors themselves and their ability to manage their respective intramural programs will also be reviewed every 4 years, as is not done presently. In addition, formal reporting procedures have been developed for Scientific Directors to use in responding to the questions and suggestions that the Board of Scientific Counselors makes during the review process, and each Institute's Advisory Council will receive copies of reports related to the review. The Deputy Director for Intramural Research will also develop and issue guidelines on the conduct of the scientific review process. These guidelines will be standards rather than rigid procedures in order to allow for differences among the Institutes.

Boards of Scientific Counselors will also be established at the clinical centers. This change, which was not specifically suggested by the panel or the ACD, will address a concern raised during an earlier review of the centers about the review of research conducted there.

Research Training Program

The Broad Context of Biomedical Research Training

Institute of Medicine Report on Manpower

Dr. Joe G. Baker

Office of Scientific and Engineering Personnel
National Academy of Sciences

Dr. Baker presented highlights of the NAS report on the training and supply of biomedical and behavioral research scientists. The report is the ninth in an NAS series on the National Research Service Award (NRSA) research training program. Unlike previous studies, this one did not examine dental or nursing research because of lack of resources. This study also differed from previous ones in that, in addition to examining the academic labor market, it focused on nonacademic sources of demand, such as private industry, foundations, hospitals, and government, which have grown rapidly as a result of the growth of the biotechnology industry and the large public and private expenditures on health-related research and development during the 1980's. The study had three objectives: to determine the extent of the need for biomedical and behavioral research personnel; to assess the current training for such personnel, primarily the NRSA program; and to make recommendations on how the program should be altered.

In summarizing study findings pertaining to the extent of need for biomedical and behavioral research personnel, Dr. Baker reported that, from 1974 to 1987, potential growth in the number of biomedical scientists steadily eroded, and the surpluses of scientists that existed during the 1970's disappeared. Potential growth is defined as the difference between attrition from science—because of retirement, death, or other reasons—and the number of new Ph.D.'s produced. Since actual growth, defined as labor market demand, was greater than potential growth in the biomedical sciences, the field had to recruit scientists from other areas. Growth in the number of new behavioral scientists has also been very slow, and as the pool of currently active scientists has aged, attrition through retirement and death has risen sharply. Consequently, labor surpluses have also declined in the behavioral sciences. However, actual growth in this area has been consistently below potential growth.

New positions to be filled by biomedical and behavioral scientists will come from two sources: loss of scientists because of death, retirement, and movement to other occupations; and growth in total employment demand. The study projected that the number of new positions for biomedical scientists during the first half of the 1990's will be considerably greater than the number of new Ph.D.'s. For behavioral scientists, the projected picture is

somewhat different; that is, a small surplus of Ph.D.'s relative to the number of openings. However, nonclinical psychologists have been moving into clinical psychology, an area of high growth rates in employment and personnel shortages. If this trend continues, a shortage in research psychologists may begin to occur. In addition, although data on physician scientists were unavailable, the study committee felt that demand for physician scientists will increase with higher spending for health-related research and development, and it had anecdotal evidence that recruitment difficulties already exist in this area.

To rectify the imbalance between supply and demand for biomedical scientists, approaches to reducing the number of openings include raising salaries to prevent movement out of science into other occupations and making institutional changes to retain women, who have a higher rate of attrition than men in the work force. Strategies to increase the number of Ph.D.'s include reducing the time necessary to get a degree, attracting foreign students, and reducing the attrition rate of students in graduate school. Dr. Baker noted that 60 percent of the students who enter graduate school do not complete their studies.

The study committee's assessment of current training programs relied primarily on 16 previous studies of the NRSA training system, none of which was rigorously controlled. All these studies indicated that NRSA trainees perform better than scientists who were not NRSA trainees with respect to outcomes such as number of articles published, receipt of postdoctoral fellowships, graduation rate, and time to obtain a degree. Whereas it is not possible to ascertain whether these outcomes are related to the training itself or to the trainee selection process, Dr. Baker believed the results of the studies suggest that the training programs were selecting the best students as NRSA trainees.

Based on their finding of a current labor shortage in the biomedical sciences and the projection that this situation will be exacerbated in the future, the study committee recommended increasing predoctoral support in the Ph.D. biomedical training programs. Although the labor market and employment needs in the behavioral sciences were projected to retain the balance that currently exists, the committee recommended maintaining training in the behavioral sciences at current levels because of its strong belief in the growing importance of such behavior-related health problems as cancer, AIDS, and alcohol and other drug addictions. The committee also recommended maintaining training for physician scientists at current levels, but it suggested more rigorously evaluating the success of such training programs. Studies of student recruitment and retention, controlled studies of former trainees, and studies of women and minorities, as well as specific improvements in data sets and information, were also recommended.

Discussion

During their discussion of the NAS study report, Committee members and Council representatives requested and considered further information about several factors that may influence the supply of scientists. One issue raised was the impact that the change in the mandatory retirement law might have on supply. Dr. Baker indicated that while this change had not been considered in the development of study projections, other analyses have found a large one-time effect on retirement rates, after which the impact of the change was fairly low. Further, even if this change increases the retention of scientists, it would not be likely to influence the supply significantly. A related issue raised was the impact of retirement in the 1990's and into the 21st century of the "bulge" of scientists hired in the 1960's. The NAS study found that, compared with an annual loss of 700 scientists in the 1970's and just over 1,000 scientists in the 1980's, 1,600 retirements are projected annually for the 1990's. Given that the number of new biomedical science Ph.D.'s is 4,000 annually,

this projection means that after the openings created by retirement are filled, only 2,400 new scientists will be available for growth or to replace scientists who change occupations.

However, Dr. Baker did not see demographic factors such as the baby boom as having a major influence on the number of persons who enter science since only a very small portion of the population enter graduate school. Instead, interest in science is more likely to influence people to enter graduate school. Nonetheless, the baby boom will have an effect on the demand for faculty in the late 1990's when the baby boomers' children will be entering universities at the same time that the faculty who taught the baby boomers will be retiring.

Funding issues affecting the supply of scientists were also considered during the discussion. The Director of the National Institute on Aging noted that there are more training applicants than there are funds available for training, and Council representatives and Committee members suggested that potential students may perceive the greatly reduced funding rate for R01 grants as a sign of a lack of career opportunities. In the United Kingdom, for example, a 90-percent drop in applications for graduate positions was directly related to the lack of job opportunities. The negative impact of the current funding climate in the United States on young investigators was also noted, and it was suggested that any study of training needs must consider actual job opportunities. In response to these concerns, Dr. Baker agreed that the current funding climate was particularly difficult for young investigators, but he also noted that when the total amount of funds available and the total number of scientist years of effort produced are examined, there is still growth in these areas. Dr. Raub also pointed out that the current NAS report had a mandated focus on training programs and that NAS is now in the early stages of a study of young investigators that will examine some of these funding issues.

Funding issues also emerged in a discussion of attrition from graduate programs and from science. In agreeing with a Council member's suggestion that lack of financial support could be responsible for the high rate of attrition from graduate school, Dr. Baker noted that more financial support could not only assist in retaining students who are already in school but could also encourage them to enter training. More information about the difference in attrition from science between men and women was also requested. The NAS study found that for men and women who had their degree 10 years or longer, approximately 95 percent of the men versus 82 percent of the women were still involved in science full time. Dr. Baker noted that the supply situation could be improved if a greater percentage of women were retained.

The projected lack of growth in Ph.D.'s entering the academic sector was another subject of concern during the discussion. A Committee member noted that the moderate growth expected in the academic sector will inhibit the enrichment necessary in science and may mean that in 10 years NIH will not be able to purchase the same amount of research from the academic sector that it can purchase now. Dr. Baker agreed and suggested that because of this possibility, the risks related to producing too few scientists are greater than the risks attached to producing too many.

Discussion also focused on issues related to evaluating the success of training programs. Clarification about criteria used and comparisons made to measure success were requested. Dr. Baker noted that while a few studies have used matched comparison groups to evaluate training, comparison or control groups are the Achilles' heel of this area of evaluation. He also argued that a major impact of the NRSA training system may not be on the individual students who receive NRSA funding, but rather on the department that receives the funding and on other students there. Better faculty and better students not on training grants can be attracted by such departments, and intellectual vitality in the

classroom can be improved. Further, if some students are given NRSA support, other students can move into teaching or research assistantships. Consequently, all students in an NRSA-funded department may benefit, not just the top ones who receive NRSA support. These impacts may be difficult to evaluate. The definition of the training program for biomedical scientists was also discussed. A Council member suggested that, at least in the academic setting, the early career years should be considered as part of the training period.

Study of M.D./Ph.D. Training

Dr. Paul Jolly

Associate Vice President for Operational Studies
Association of American Medical Colleges

Dr. Jolly presented preliminary findings of a study on M.D./Ph.D. training being conducted by AAMC. The study is examining both NIH and non-NIH supported training to ascertain the number of M.D./Ph.D. students who enter training, the number of students who complete training and obtain both the M.D. and Ph.D., their characteristics, and the manner in which they differ from those students not involved in M.D./Ph.D. training.

In describing the study, Dr. Jolly emphasized current limitations of available data. The research is using data in an AAMC data base that tracks medical students through the residency. All students who apply to a medical school through the AAMC centralized application service are included in the data base. The association also administers questionnaires to all graduating seniors of medical schools; this questionnaire, for which there is a 70-percent return rate, asks whether students are in a Ph.D. program. Because non-AAMC schools also report on applicants to the AAMC, students who apply only to non-AAMC schools are also included in the data base. However, data on this group are less complete. Consequently, some of the students in this group who enter medical school with a Ph.D. may not be distinguished from those who complete the Ph.D. while in medical school. Further, complete data may not be available for students who enroll in medical school with the Ph.D. with advanced standing and therefore do not apply through the centralized application system. The association is now attempting to remedy these data limitations by requesting that individual M.D./Ph.D. program coordinators verify students involved in their programs.

Results of the preliminary analysis of data from 1980 to 1990 indicate that the number of minorities considered by the AAMC as underrepresented in medicine—that is, blacks, Mexican-Americans, mainland Puerto Ricans, and American Indians—who are in M.D./Ph.D. programs has remained very small while the percentage of Asians is increasing. M.D./Ph.D. students are more likely to marry by the time they graduate than are medical students in general, possibly because of the greater length of time involved in an M.D./Ph.D. program. Other preliminary results not only confirmed a high level of involvement of M.D./Ph.D. students in research-related activities both while in medical school and in their plans for future careers, but also suggested that a more than negligible number of medical students had been or were planning to be involved in such activities. Most M.D./Ph.D. students reported that they participated in a research project during medical school. Although the percentage of students in general involved in such a project was considerably less, this percentage has increased steadily over the study period. Most M.D./Ph.D. students also reported they had authored or coauthored a research paper while in medical school; approximately 25 percent of all medical students had done so. The great majority of M.D./Ph.D. students planned to take a research fellowship after graduation from medical school; the percentage of all medical students reporting such plans ranged from 20 to 25 percent over the study period. Most M.D./Ph.D. students also reported that they planned to spend 25 percent or more of their time in research after they completed training;

fewer than 20 percent of all students indicated that they planned this level of research activity.

Discussion

During the discussion of the AAMC study on M.D./Ph.D. training, a Committee member requested clarification about the sources of funding of the M.D./Ph.D. students tracked by the AAMC. In response, Dr. Jolly noted that the AAMC was currently working with the National Institute of General Medical Sciences (NIGMS), which provides support for M.D./Ph.D. training, to determine the proportion of students supported by NIH and the proportion supported by other funding sources. Informal surveys of M.D./Ph.D. program directors have indicated that at some schools that receive NIH funding for M.D./Ph.D. training, there are some M.D./Ph.D. candidates who do not receive NIH support. There are also institutions that have M.D./Ph.D. programs but receive no NIH support at all.

In relation to this issue, Dr. Kirschstein, the Director of NIGMS, reported that the Institute supports 129 M.D./Ph.D. programs in 29 medical schools around the country. Although in some of these schools NIH funds are available for only half the students that the institution wishes to enroll in M.D./Ph.D. training, this funding enables the institution to put into place a curriculum and training process upon which it can build. While for many years approximately 630 students received funding annually, considerable pressure to increase that number has led to 735 students now being funded across all years of training. The training program takes about 6 1/2 to 7 years to complete; students receive support for a maximum of 6 years.

The patterns and outcomes of training for M.D./Ph.D.'s were another focus of the discussion. Dr. Kirschstein summarized data on long-term outcomes of a small cohort of Medical Scientist Training Program (MSTP) participants; these data indicated that 88 percent of the participants were in academic medicine and had grant approval and award rates believed to be significantly better than those of all NIH R01 applicants. One Committee member emphasized that the real assay point for the AAMC study must occur 3 to 8 years after graduation, when the career commitments of trainees can be more accurately evaluated. Another suggested that the outcomes of individuals who complete the M.D. and then participate in short-term research training should also be tracked and compared with the outcomes of those who receive M.D./Ph.D.'s. Dr. Jolly indicated that to evaluate long-term outcomes of M.D./Ph.D. training, faculty rosters of all medical schools will be scanned to ascertain the number of those faculty members who received M.D./Ph.D. training. Literature data bases such as Medline could also be examined to document the publication rates of those who received such training. Similar outcomes will be examined for the Medical Scholars Program and the Cloisters Program; for the most part, individuals in these research training programs do not receive Ph.D.'s. There are also plans to determine whether the M.D. and Ph.D. degrees were received simultaneously by those in the study sample and, if not, the order in which they *were* received. Relationships of these patterns of training to outcomes will be examined as well.

During the discussion, Dr. Kirschstein responded to an Advisory Committee member's question about the distribution of specialty interests of M.D./Ph.D. students. She noted that for the NIH MSTP program, the vast majority of graduates are in departments of internal medicine. The remainder are spread out over a variety of specialties, with the next greatest number in pediatrics. Most of these graduates go on to do house officer training and plan to take specialty boards, either in internal medicine or in subspecialties. Recently, a number of students wishing to conduct research during this latter stage of training selected pathology as a way to combine research with the demands of internal medicine.

*Report of the Association of American Universities,
"The Ph.D. Shortage: The Federal Role"*

Dr. Robert Rosenzweig

President

Association of American Universities

Dr. Rosenzweig shared his observations on the AAU's report, "The Ph.D. Shortage: The Federal Role," and related issues. He noted that the report is based on a number of independent analyses that have reached similar conclusions—namely, that there will be substantial shortages of Ph.D.'s across all disciplines and in all employment markets in the latter part of this decade and into the next century. Underlying these shortages is an increase in industrial demand for scientists and engineers and an increase in academic enrollment.

Although the number of Ph.D.'s awarded in this country has remained fairly stable since the mid-1970's, the proportion of U.S. citizens earning doctorates declined for two decades until 1988, when a slight increase occurred. From one perspective, this is a positive situation since some of those from outside the United States whose primary, secondary, and collegiate education was paid for by non-U.S. sources have entered the U.S. labor market, at least temporarily. However, the AAU believes this to be an unstable base on which to build a national science policy. As regimes around the world become more liberal and economic growth is stimulated in parts of the world now supplying this country with graduate students, these students may find the possibility of returning to their homelands to apply their education more attractive and they will be more likely to do so. Thus, the AAU believes it desirable to increase the number of American nationals who enter Ph.D. programs and then the labor market.

Dr. Rosenzweig noted a correlation between the decline in the number of U.S. citizens earning Ph.D.'s and the decline in Federal support of Ph.D.-level education. From 1969 to the present, the number of federally funded fellowships and traineeships fell from approximately 60,000 to fewer than 13,000. While the NIH NRSA program is the largest for the funding of training and supports almost half of those 13,000 students, NRSA stipends are among the lowest of all Federal programs.

To address the projected shortages, the AAU has initiated a program of advocacy to increase Federal support for Ph.D. education. This program calls for doubling the number of fellowships and traineeships. However, this increase should not result in the training of too large a cohort, as occurred in the 1960's and 1970's, since doubling the current number would bring the total up to approximately 26,000—far less than the 60,000 fellowships and traineeships that were being awarded at the peak during the 1960's. This program has also requested an increase in research assistantships, new strategies to increase participation by non-Asian minorities and women, expanded and flexible support of research, and direct funding for research facilities and instrumentation. The association believes that this total package is necessary to attract new students to academic or scientific training and careers.

The second part of the AAU program grows out of the recognition that institutions, rather than the Federal Government, have the primary responsibility for addressing the projected shortages. They can meet this responsibility by dealing more effectively with student attrition from graduate programs and by reducing the time necessary to complete a degree, which has continued to grow in all fields. While lack of stipends may have some impact on length of time in training, Dr. Rosenzweig argued that the relationship between the student and his or her thesis adviser is the most important determining factor and that this relationship has deteriorated over the years. A common understanding of the requirements for a Ph.D. dissertation, if it ever existed, has also been lost as some schools now

require dissertations to be completed pieces of scholarship—that is, a publishable book or an already published article—rather than evidence of the ability to conduct independent research.

While the response of the academic community to the AAU's public policy recommendations has been mainly positive, there is some resistance to the current perception that the country is now too poor to pay for the necessities of life, much less to make the investments required to provide for their enhancement in future decades. This perception of limited resources has led to concern that money spent on training means less spent on research. However, it is Dr. Rosenzweig's belief that universities are not research "job shops" but rather educational institutions with a responsibility for educating and training students that is at least as important as their obligation to provide new knowledge. Further, universities should reach for available resources and take advantage of a climate receptive to increased funding for training. He also noted that while there is concern about overproduction of Ph.D.'s as occurred 20 years ago, there is at present no unemployment among Ph.D.'s.

Discussion

The question of non-U.S. citizens entering training in various disciplines was one focus of discussion about the AAU report. A Council representative took exception to the report's statement that "it is unwise national policy to rely so heavily on imported talent and to fail to develop our own intellectual resources," noting that the United States has historically depended on influxes of people from other countries. In addition, he questioned whether this pattern of events is properly termed "national policy."

In response, Dr. Rosenzweig argued that while there is no national policy on this matter, policy can be inferred from behavior. Further, while he acknowledged that this country's great source of strength has been its ability to attract and absorb immigrants who have contributed enormously to scholarship and to life in general, individuals who come to this country for training are not immigrants in the classic sense. For the most part, they do not come here to become American citizens but rather to go to school, and it is risky, therefore, to base national policy on the assumption that these individuals will behave like previous groups of immigrants. He agreed, however, with the Council representative's point that the validity of this assumption is still unknown and may prove to be correct.

Financial support of biomedical research training and institutions was another focus of discussion. A Council representative noted that while the AAU report examined support of graduate students across all disciplines, funding in the biomedical fields differs from that in other academic fields. Dr. Rosenzweig agreed noting that the proportion of Federal funds supporting training is greater in biomedical fields than in any other field. Institutional funds supporting training in this area are also often indirectly derived from Federal support.

Report on the Review of the NIH Biomedical Research Training Programs

Physician Scientist Training

Dr. Jay Moskowitz

Associate Director for Science Policy and Legislation
National Institutes of Health

After reviewing the history of NIH research training programs, which began with the legislation that formally established the then National Institute of Health in 1930,

Dr. Moskowitz noted that the fundamental goal of these programs is to prepare well-trained, highly qualified, and productive research investigators in fields relevant to the advance of biomedical science. The NRSA program, established in 1974, is currently the only authority under which NIH supports training of persons for careers in biomedical sciences. The charge to the Task Force on Physician Scientist Training, and to the other task forces as well, was to identify and assess issues related to the development of physician scientists and to make recommendations for improvements.

After examining the early recruitment of talented individuals into research careers, the task force found that inadequate numbers of individuals with professional doctorates—that is, M.D.'s or other professional doctorates—are entering biomedical research careers. Studies of short-term training for health professional students—for example, the NIH T-35 program—indicated that these programs are effective in stimulating interest in research careers. However, only one NIH Institute, the National Institute on Neurological Disorders and Stroke, supports short-term traineeships in its institutional NRSA training grants for professional predoctoral students. The task force believed that expanding opportunities for predoctoral research experiences as part of institutional training grant programs will enhance early recruitment efforts. Accordingly, it recommended that “professional predoctoral students should be eligible for training on institutional training grants during the summer or elective time for periods of between 3 and 12 months with a maximum of 12 months. A minimum of 6 months should be encouraged.”

The task force also addressed the length of research training required to prepare professionally trained individuals for independent research careers. Application for and receipt of NIH research grant support is an important measure of an individual's level of research development. Data on M.D.'s who received postdoctoral research training for 12 months or less, for 12 to 24 months, and for more than 24 months documented a strong relationship between the duration of postdoctoral research training and the likelihood of applying for and being successful in receiving NIH independent research support. The task force concluded that 12 months of postdoctoral research training is inadequate to prepare most individuals for independent research careers and that training in most cases should extend for a period of up to 5 years. It was further believed that requiring a minimum of 2 years of research training will increase the likelihood that those individuals accepting appointments have a real interest in research careers. A modification of the payback requirement so that it is incurred in the first training year and satisfied by the completion of the second training year should provide trainees with incentive to complete the minimum appointment period.

The task force also decided that optional appointments for a third or fourth year of training under a T-32 NRSA training grant should be allowed. However, there was concern about the appropriateness of delegating to the training directors the decision to extend training beyond the first 2 years, and it was believed that third- and fourth-year appointments should require an NIH review. In other instances, trainees may be ready and would be encouraged to apply for support from competitive funding programs—for example, the F-32 NRSA individual fellowship grant, the FIRST (First Independent Research Support and Transition) Award, or an R01. The task force also concluded that a 3-year K-series career development award should be implemented; when coupled with the initial T-32 2-year training experience, it will provide professional doctorates with the total of 5 or more years of research experience deemed necessary to prepare them for a successful research career. It was also concluded that salaries for K-series awards should be higher than corresponding stipends for training grant appointments to provide incentive for trainees to seek independent support through national competition.

Based on these conclusions, the task force made the following recommendations:

- A minimum of 2 years of training should be required for all professional doctorate appointees to institutional NRSA grants. Trainees should be encouraged to apply for further research training and career development through national competition. Training grant appointments may be extended beyond 2 years upon the recommendation of the training director and with NIH concurrence.
- The NIH/Department of Health and Human Services (DHHS) should plan to modify the payback requirement of the NRSA reauthorization legislation.
- Three-year K-series awards should be made available for professional doctorates, and salaries should be increased to \$50,000 per year.

The task force also recognized that any revision to the existing training structure would have to be compatible with the requirements for board certification. Based on information received from representatives of the scientific community familiar with clinical training requirements for board certification, the task force concluded that a revised research training structure can be effectively integrated with the requirements for clinical training, endorsed a flexible approach accommodating differing needs and preferences for clinical training, and recommended that "multiple pathways should be permitted to accommodate the needs for clinical certification within the context of the research training experience of 2 or more years."

Because available data demonstrate no relationship between training program size and subsequent development of trainees into independent investigators, the task force agreed that NIH should not arbitrarily limit the number of trainees permitted on a training grant and recommended that "numbers of trainees in training programs should be consistent with individual ICD (Institutes, Centers, and Divisions) policy and the institution's resources."

However, available data indicate that M.D.'s trained in programs that also train Ph.D.'s are more likely to apply for and receive independent NIH support than M.D.'s trained in programs with only other M.D.'s. The task force therefore recommended that "the presence of both M.D. and Ph.D. trainees in the same program should be considered favorably in the review of NRSA training grant applications."

Finally, the task force on physician scientist training recommended that

- Special training experiences away from the training institution may be proposed as part of a training grant application or subsequently to NIH staff; and
- Review of competing renewals for NRSA training grants should focus on trainee performance as it relates to preparation for a productive research career.

Training in Clinical and Community-Based Study Designs and Methodology

Dr. Curtis Meinert

Johns Hopkins School of Hygiene and Public Health

Dr. Meinert, a member of the National Advisory Eye Council and of the Task Force on Training in Clinical and Community-Based Study Designs and Methodology, discussed recommendations of that task force. It focused on the training of physician scientists as well as on undergraduate doctoral training to prepare scientists for leadership and support roles in clinical trials, epidemiological followup studies, and large-scale multicenter studies.

During its deliberations, the task force observed that there has been limited growth in the production of biostatisticians and epidemiologists: 44 persons received Ph.D.'s in biostatistics in 1979 and 47 in 1988. For epidemiologists, 76 received Ph.D.'s in 1983 and 99 in 1988. Further, the demand for personnel to become involved in clinical trials and epidemiological studies exceeds the supply of those with appropriate training, and existing degree programs are not prepared to meet the needs of physicians who want additional training. Consequently, such individuals generally enroll in schools of public health for 1-year Master of Public Health programs that provide broad but nonintensive training in epidemiology, biostatistics, and policy.

Graduate training in traditional departments of biostatistics and epidemiology does not really prepare students for community-based or multicenter research. While students of biostatistics are well trained in methods and procedures, they do not receive extensive training in the art and science of data collection per se. On the other hand, training of epidemiologists emphasizes data collection but is weak in methodology. Moreover, the training model for each of these disciplines does not prepare students for work in a collaborative setting.

The task force concluded that training programs are needed that focus on epidemiology, biostatistics, and related topics, including hands-on experience at various stages of ongoing clinical trials and epidemiologic research as well as didactic work. Such training should include master's programs, predoctoral programs leading to the Ph.D., and—primarily for physician scientists—nondegree certificate programs. In addition, courses and seminars relevant to participation in this type of research—for example, courses addressing data collection and data systems design, the ethics of design, meta-analysis, and the art and science of collaboration—do not exist and need to be developed.

In line with these conclusions, the task force recommended that “advanced programs of study and K-series awards should be supported in epidemiology, biostatistics, or related topics to increase predoctoral and postdoctoral research training opportunities. Current NIH mechanisms also should be used to support master's degree-level programs and nondegree certificate programs that focus on these topics.”

Predoctoral and Postdoctoral Training of Nonphysician Scientists

Dr. Ruth Kirschstein

Director

National Institute of General Medical Sciences

Dr. Kirschstein summarized the recommendations of the Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists. She noted that while there were considerable problems regarding the issues addressed by the other task forces, the training of nonphysician scientists had been relatively free of problems. Nonetheless, there were some issues that needed to be addressed.

First was the question of tuition for predoctoral students. Since the inception of the NIH research training programs, there has been a commitment to provide full tuition and related fees for predoctoral students. Since the passage of the National Research Service Award Act in 1974, however, limitations have been placed on the amount of fees to be paid above and beyond tuition. Further, in the past two decades, tuition charges for predoctoral students have risen at about 10 percent a year. This has led to sharp reductions in the number of predoctoral students supported. Consequently, several of the Institutes have had to freeze tuition costs to sustain their training programs. Another policy that was implemented to address this problem was the limiting of tuition increases to 6 percent in the

noncompeting years before renewal of training grants. While this policy produced some reductions, the new tuition levels set at the time of renewal made up for the difference.

Many of the other Federal agencies do not pay full tuition costs for the trainees and fellowships they support but rather provide a flat fee or a cost of education allowance. A committee of NIH staff presented a proposal to the task force recommending that NIH provide a cost of education allowance for each predoctoral trainee. However, because NIH has long been committed to paying full tuition, the task force felt that a sudden change from full payment could have a drastic impact. It therefore suggested a two-tier system, with one tier based on current charges for public institutions and the other for private institutions, as was previously proposed by the NIH Committee on Payment of Tuition for Research Training. The task force recommendation was that "the proposed two-tier cost of education allowance as a mechanism to limit tuition payments is reaffirmed. The same general principles should be applied to special NIH research training programs."

The training stipends paid by different Federal agencies vary considerably. Although the NIH predoctoral stipend has recently been raised to \$8,500, it is the lowest among the Federal agencies. It was suggested that the NIH stipend be raised to \$10,000 but only if new funds are available. It was also recognized that stipends for postdoctoral training should be equivalent to house staff salaries. The task force has proposed the same stipends for post-M.D.'s and post-Ph.D.'s. Accordingly, the task force recommended that "postdoctoral stipends for professional doctorates should be at least as attractive as current house staff salaries. Stipend levels should also be increased for academic trainees. Annual stipend increases are necessary to compensate for increased living costs."

With regard to training stipends, the task force also recommended that "Federal agencies supporting biomedical research training should explore ways of making the mechanism of support more equivalent."

The task force also believed that, to assess the success of past and current training endeavors appropriately and accurately, improved data collection procedures are required. It was therefore recommended that

- Standardized information necessary to assess program performance should be collected on all individuals and institutions receiving NRSA research training support; and
- Available NIH training data should be analyzed further and new data bases established as needed.

Finally, the task force believed that although funds are limited, possible new approaches to training should be examined. For example, individual predoctoral fellowships, which were funded by NIH before the National Research Service Award Act and which are being used effectively in other components of the Public Health Service, have the potential to complement existing NIH predoctoral training grants by expanding the number of institutions involved in training. Consequently, the task force recommended that

- The opportunity for individual predoctoral fellowships to address specific NIH training needs should be reviewed; and
- Needs in new research areas and approaches that enable NIH research training to respond to these needs should be evaluated on an ongoing basis.

Discussion

Council representatives varied in their beliefs about the appropriate minimum amount of time for a predoctoral research experience. A member of the Arthritis, Musculoskeletal, and Skin Diseases Council indicated that it was the consensus of that Council that the proposed maximum of a 12-month predoctoral training experience may be inadequate for some potentially excellent physician scientists and that an effort should be made to encourage a longer term minimum of, for example, 6 months and a maximum of 18 to 24 months. However, another member believed that while a 3-month commitment is appropriate for stimulating a level of interest in research that may ultimately lead to a research career, forcing a commitment of 6 months at the predoctoral level may reduce the probability of some students becoming involved in research training at that level.

Council representatives and Committee members emphasized the need for flexible approaches to providing Ph.D.-level training for professional doctorates. One issue raised was the impact 2 years of research training may have on clinical training. Concerns were also expressed by Council representatives about the recommended 2-year minimum appointment for postdoctoral training and the related payback requirement. If directors were required to make all appointments for 2 years, fewer individuals would be trained. It was noted that while most basic science departments generally do not accept trainees for less than 2 years, a person may be appointed to a T-32 training grant for 1 year and moved to another source of funding for the second year. It was suggested that additional options such as other Federal research awards or employment as Federal research scientists should be incorporated into the recommended payback modification to satisfy the second-year payback requirement. In response to this latter point, Dr. Moskowitz noted that while such possibilities were not included in the task force report, they were considered during deliberations and could be incorporated into the mechanism developed by the Office of Extramural Research to implement this recommendation.

The recommendation pertaining to tuition for predoctoral trainees stimulated considerable discussion by Committee members and Council representatives. It was noted that while other components of a university have various sources of support, costs in the medical centers cannot be easily shifted. Further, although there have been sharp increases in tuition over the last decade, these cover real costs. If a cap is placed on tuition, covering these charges will lead to a reduction in other institutional training efforts. A Committee member suggested that less rigid approaches should be considered—for example, linking tuition increases that are to be met by the Federal Government to other appropriate parameters such as undergraduate tuition.

In response, Dr. Kirschstein acknowledged that all the alternatives considered by the Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists were found to have a negative aspect. Dr. Raub also noted that in discussions on this topic, stereotypic views tend to be presented. University presidents emphasize the need for full costs and are willing to enroll fewer students, while chairs of basic science departments argue that numbers of trainees are critical and that the institution will somehow cover the extra costs. The two-tier system recommended by the task force was believed to be a compromise that was at least more compatible with previous NIH policy than the contribution to the cost of education that other Federal agencies have adopted. However, it was also acknowledged that this approach was not likely to lead to an increase in the low number of trainees, which some Council representatives and Committee members viewed as a more serious problem than the tuition issue. Rather, the two-tier system will allow NIH training programs to be sustained. However, Dr. Raub noted that the recommended caps are parameter values that can be adjusted each year in keeping with the budget and that, therefore, this is a flexible approach.

The recommended increase in stipends was also a topic of discussion. Concern was expressed that while such an increase may be instituted to attract more students, the reverse may occur because the higher stipend amounts may require the total number of training slots to be decreased. A Council representative suggested that NIH determine a maximum stipend level but give training directors discretion in the amount provided to specific individuals since some trainees may enter the system with lower stipend levels and some support from another source. This approach would allow the program director to use funds to maximize the number of trainees. The possibility of having built-in inflationary costs in the training stipends, such as those included in the T, K, and R01 awards, was also raised. However, it was noted that while this approach has been previously proposed, necessary funds have not been appropriated.

Report of Activities to Implement Recommendations Contained in the Review

Dr. George Galasso

Acting Deputy Director for Extramural Affairs
National Institutes of Health

Dr. Galasso reported on the activities that had been undertaken to implement the recommendations contained in the Review of the NIH Biomedical Research Training Programs. In so doing, he summarized the comments of the National Advisory Councils and Boards pertaining to each of the recommendations:

- Professional predoctoral students should be eligible for training on institutional training grants during the summer or elective time for periods of between 3 and 12 months with a maximum of 12 months. A minimum of 6 months should be encouraged.

While the majority of Councils responding agreed with the recommendation about training for professional predoctoral students, the Board of the National Cancer Institute (NCI) cautioned that funds for this training could be misused to supplement undergraduate thesis funds and would also reduce funds available for traditional research training.

- A minimum of 2 years of training should be required for all professional doctorate appointees to institutional NRSA grants. Trainees should be encouraged to apply for further research training and career development through national competition. Training grant appointments may be extended beyond 2 years on the recommendation of the training director and with NIH concurrence.
- NIH/DHHS should plan to modify the payback requirement of the NRSA reauthorization legislation.

Most Councils responding also agreed with the recommended 2-year training minimum and modification of the payback requirement. Comments received related primarily to the payback requirement. It was suggested, as had also been noted earlier in the meeting, that payback through appropriate means other than a second year on an NRSA training grant should be possible. There was also concern that those who wanted or needed only 1 year of training would avoid such training if payback were required for less than 2 years of training.

Submission of a legislative proposal is necessary to modify the payback requirement. A proposal has been submitted, but no further action has occurred.

- Three-year K-series awards should be made available for professional doctorates. Salaries should be increased to \$50,000 per year on these awards.

All responding Councils favored this. The 3-year award has been announced in the *NIH Guide*, and funds to cover the proposed increase in salaries have been requested.

- Multiple pathways should be permitted to accommodate the need for clinical certification within the context of the research training experience of 2 or more years.

Most of the responding Councils also favored this recommendation. Some concerns were raised, however, about the effect that 2 years of research training may have on the clinical training of those involved. The American Board of Internal Medicine has indicated that mechanisms exist to allow the incorporation of research training while ensuring proper clinical training. The American Board of Psychiatry and Neurology has also been approached to determine the flexibility in those specialties.

- The presence of both M.D. and Ph.D. trainees in the same program should be considered favorably in the review of NRSA training grant applications.

All responding Councils favored this recommendation. No further action other than encouragement by the ICD's of their grantees is needed to implement the recommendation.

- Special training experiences away from the training institution may be proposed as part of a training grant application or subsequently to NIH staff.

All responding Councils favored this recommendation. No further action other than encouragement by the ICD's of their grantees is needed to implement the recommendation.

- Review of competing renewals for NRSA training grants should focus on trainee performance as it relates to preparation for a productive research career.

All responding Councils supported this recommendation. An NIH-wide work group has been established to develop procedures for grant applicants to use to document the career patterns of former trainees in their applications.

- Advanced programs of study and K-series awards should be supported in epidemiology, biostatistics, or related topics to increase predoctoral and postdoctoral research training opportunities. Current NIH mechanisms should also be used to support master's degree programs and nondegree certificate programs that focus on these topics.

All responding Councils supported this recommendation. A legislative proposal would be needed to initiate support of master's degree and certification programs. Proactive efforts are also needed to encourage training in these areas.

- The proposed two-tier cost of education allowance as a mechanism to limit tuition payments is reaffirmed. The same general principles should be applied to special NIH research training programs.

Most of the responding Councils were in favor of this proposal. However, the NCI Board expressed concern about underfunding the full costs of research training and believed this approach might be inappropriate. No further action has been taken on this recommendation.

- Postdoctoral stipends for professional doctorates should be at least as attractive as current house staff salaries. Stipend levels should also be increased for academic

trainees. Annual stipend increases are necessary to compensate for changes in living costs.

All responding Councils favored the recommendation to increase stipends, and four of those responding also suggested that the stipends should be increased even if it results in the training of fewer individuals.

- Standardized information necessary to assess program performance should be collected on all individuals and institutions receiving NRSA research training support.
- Available NIH training data should be analyzed further and new data bases established as needed.

All responding Councils agreed with the recommendations for improved data collection efforts. The NIH Training Activities Committee is developing a standardized reporting mechanism for capturing information to develop needed data bases.

Discussion

Following the presentations and related discussion, the final deliberations of Committee members and Council representatives on the review of the NIH biomedical research training programs took place. These deliberations began with some observations by Advisory Committee member Mr. Rodney Nichols, Executive Vice President of Rockefeller University, on the NIH training program review and related topics considered at the meeting.

As an introduction to his observations, Mr. Nichols expressed appreciation for the efforts involved in the review of the NIH biomedical research training programs, which he believed documented the seriousness with which NIH is taking the current national problems related to training. However, he noted that, as indicated in the NAS study report, essential baseline data are lacking and more funds should be spent on gathering this information. If such data had been available for the past 25 years, planning for the future might be easier. He also noted that the Federal view should be compared with the rather different perspective of major research centers, such as Rockefeller University, which, he believed, would be willing to participate in an evaluation effort by providing advice and the results of their own data collection efforts. In addition, measures of success in training need to be clarified, an issue that was not addressed in the review of NIH training programs. Publications in refereed journals and receipt of R01 grants are two frequently mentioned indices. If these are considered to be the primary measures of success, this fact should be stated, and data on these measures should be systematically gathered. Similarly, if other measures are believed to document success, this should be explained as well and relevant data collected.

Consideration of Individual Task Force Recommendations

The Committee then turned to consider the individual recommendations made by each task force to determine which recommendations achieved a general consensus and to further consider issues related to particular recommendations.

- Professional predoctoral students should be eligible for training on institutional training grants during the summer or elective time for periods of between 3 and 12 months with a maximum of 12 months. A minimum of 6 months should be encouraged.

There was a general consensus in favor of this recommendation. Discussion focused primarily on the calculation of the time period for training. While there was agreement that the recommended 6-month training period could be split into two 3-month periods, a training period based on the totaling of evening, weekend, and other odd hours was viewed as logistically impossible to track. Further, except in special circumstances, it was believed a student working in an active laboratory at odd hours would find it difficult to sustain a true research project.

- A minimum of 2 years of training should be required for all professional doctorate appointees to institutional NRSA grants. Trainees should be encouraged to apply for further research training and career development through national competition. Training grant appointments may be extended beyond 2 years on the recommendation of the training director and with NIH concurrence.

There was general agreement with the requirement of 2 years' minimum training for all professional doctorate appointees to institutional NRSA grants. The discussion of the recommendation focused primarily on the language used. There was concern that the recommendation not be written to imply that only 2-year appointments could be made to training grants. It was suggested that the recommendation be worded to convey that the grant could be used only as part of a training program of 2 years or longer. There was also agreement on language that would encourage 2-year appointments to training programs as a matter of administrative practice.

- NIH/DHHS should plan to modify the payback requirement of the NRSA reauthorization legislation.

There was general agreement with the recommendation that the payback requirement of the NRSA reauthorization legislation be modified from its current status in which the first year of training does not incur a payback. The modified requirement would hold that if an individual trains for 2 or more years, no payback will be necessary. Dr. Raub indicated that the legislative proposal could be written to include other legitimate research experience during the second year as meeting the payback requirement.

In response to a Council representative's request for information about enforcement of the payback requirement over the years, Dr. Raub indicated that an elaborate recording system has been established that provides considerable incentive for individuals to report their status and its relationship to the requirement. The vast majority of training recipients have had no difficulty in meeting the requirement, and although some have been required to pay back the money received, their number is very small. Although Dr. Raub noted that the administrative burden involved in this tracking process is significant, he also acknowledged that the motivation underlying the recommendation was to encourage people to enter research careers and not to reduce this burden.

Council representatives and Committee members further requested information about the approach to be used in justifying the proposal and the scope of the proposal's impact. Dr. Raub stated his belief that NIH can demonstrate that it has taken the current payback requirement seriously and that the principal reason for its implementation—to discourage the support of clinical experiences under the guise of research—has not been a problem for a long time. Dr. Kirschstein also noted that there was little difficulty in receiving approval for an earlier proposal to change the requirement to allow 12 months of research training without payback; this fact suggests that the current recommendation may be successful as well. Dr. Moskowitz indicated that the modification is being recommended only for M.D.'s and that it would require concurrence by all agencies with NRSA authority, including any relevant agency of the Public Health Service.

- Three-year K-series awards should be made available for professional doctorates. Salaries should be increased to \$50,000 per year on these awards.

While no disagreement was expressed with this recommendation, various aspects of the proposal and its implications led to discussion and suggestions for refinements by Council representatives and Committee members. In response to a Council member's suggestion that the recommended salary increase occur only if funds are available, Dr. Raub noted that K-series funds come from the research grant pool and that a salary increase would therefore involve a tradeoff. Another suggestion was that the status of career development awards be changed so that their funds no longer come from the research grant pool. In response, Dr. Raub, while noting that such reevaluation of the award's status was possible, indicated that caution would be required because of the strong NIH tradition of recognizing training as a distinct activity. Dr. Kirschstein also expressed reservations about such a modification because the NRSA authorization has a ceiling on funding. Other Council representatives expressed concerns about salary figures included in the recommendation, noting that the inclusion of a specific salary figure may ultimately become a frozen benchmark and that the requested salary increase from \$40,000 (which has been in place for over 10 years) to \$50,000 does not keep up with inflation.

Based on the concern that the 3-year designation in the recommendation is unnecessarily limiting, it was proposed that more flexible language be used to describe the training period. Dr. Moskowitz suggested that the phrase "3, 4, or 5 years," which was in fact the intent of the task force, be adopted. Differences in types of K awards and the association of these differences with varying time requirements was also noted. For example, a K04 award—that is, a research development award—has traditionally been a 5-year award targeted at the trained investigator who is usually simultaneously applying for an R01 award, and the desire to reduce its length is not likely. It is also not clear whether it would be appropriate to reduce the 5-year length of the physician scientist award, which involves training in basic research laboratories followed by supervision by a monitor. The recommendation is most relevant to the clinical investigator award, and it was suggested that the language of the recommendation reflect this fact.

- Multiple pathways should be permitted to accommodate the needs for clinical certification within the context of the research training experience of 2 or more years.

There was general agreement with this recommendation. The brief discussion emphasized that the task force intended to promote flexibility wherever possible and that concurrence with the recommendation did not imply support of any specific scheme that may have been used as an example in the task force report or presentation.

- The presence of both M.D. and Ph.D. trainees in the same program should be considered favorably in the review of NRSA training grant applications.

No disagreement was expressed with this recommendation. Dr. Raub indicated that this point has never been made explicit, and there was a sense that it would be helpful to emphasize it. He also noted that some training grants have included only physicians and that some of these grants have had disappointing yields.

- Special training experiences away from the training institution may be proposed as part of a training grant application or subsequently to NIH staff.

No disagreement was expressed and no discussion was initiated on this recommendation.

- Review of competing renewals for NRSA training grants should focus on trainee performance as it relates to preparation for a productive research career.

There was general agreement with this recommendation. A Council representative emphasized that this approach should not prejudice the consideration of promising new training grant proposals.

- Advanced programs of study and K-series awards should be supported in epidemiology, biostatistics, or related topics to increase predoctoral and postdoctoral research training opportunities. Current NIH mechanisms also should be used to support master's degree programs and nondegree certificate programs that focus on these topics.

While Committee members and Council representatives agreed that M.D.'s should be supported for training in the areas of epidemiology, biostatistics, and related topics, they demonstrated a concern that directing training funds at nonprofessional degree-seeking students may not be desirable. Although the need for individuals to staff clinical trials was acknowledged, it was argued that funding the training of such individuals did not appear to be compatible with the NIH mission. It was concluded that although the Committee favored the recommendation as it relates to M.D.'s, the recommendation required further internal attention with respect to its relevance to the training of other persons.

- The proposed two-tier cost of education allowance as a mechanism to limit tuition payments is reaffirmed. The same general principles should be applied to special NIH research training programs.

Discussion focused on the perception of an NIH shift from the use of an investment strategy in its funding approach—that is, investment in people and institutions—to an approach driven by exigency. Related to this was the belief that the identification and funding of the minimum number of trainees necessary to sustain the research enterprise was of paramount importance yet had not been identified in any of the task force recommendations. In response, Dr. Raub indicated that the importance NIH places on maintaining a sufficient number of trainees has led to the need to place greater restraints on stipend levels and tuition reimbursements. This policy is also implicit in the President's budget for fiscal year 1991, which proposes 12,000 trainees along with a continued restraint on stipend level and the two-tier tuition cap.

The Committee did not reach a consensus on the tuition issue, and it encouraged NIH staff to continue to work toward a fair and balanced mechanism for addressing this problem.

- Postdoctoral stipends for professional doctorates should be at least as attractive as current house staff salaries. Stipend levels should also be increased for academic trainees. Annual stipend increases are necessary to compensate for changes in living costs.

While no disagreement was expressed with this recommendation, Council representatives and Committee members emphasized that the recommended increase for predoctoral stipends should occur only if new funds are available. The primary focus of discussion was on the possibility that the prohibition against supplementing stipends with Federal funds could be lifted. Council representatives and Committee members saw this proposal as a means to address large salary discrepancies and thereby to increase the probability of attracting M.D.'s into a research training program.

Dr. Raub reviewed two aspects of the rationale for the prohibition. First, training and research are authorized separately by Congress, and by regulation, DHHS has endeavored

to ensure that these two discrete authorizations are not intertwined in any way that would be seen as contrary to the intent of Congress. Some also feared that the concept of stipends would be eroded if such supplementation could occur, and that this could lead to a reduced commitment to stipends and to greater movement toward apprenticeship models, which have been used by other research agencies as well as by NIH. However, Dr. Raub believed that reopening the question would be appropriate, and it was concluded that, on the Committee's recommendation, NIH staff should assess the feasibility and desirability of a change in the prohibition.

- Standardized information necessary to assess program performance should be collected on all individuals and institutions receiving NRSA research training support.
- Available NIH training data should be analyzed further and new data bases established as needed.

Although no disagreement was expressed with these recommendations, some issues were raised by Council representatives. The representative from the National Advisory Environmental Health Council noted that a substantial proportion of the trainees of the National Institute of Environmental Sciences are employed in industry as toxicologists and pathologists; the representative indicated that appropriate measures are needed to evaluate the contribution of this training, which may not be measurable using R01s or publications. The representative was assured that this need was well understood by the task force responsible for the recommendation. In response to concern expressed about the source of funds that would be used to enhance the data collection process, Dr. Raub acknowledged that funds would have to come from the operating budgets of the Institutes or from grant or contract lines. He also pointed out that the Paperwork Reduction Act, implemented over 10 years ago, severely restricted the information collection activities of Federal agencies. Although not offered as an excuse, this legislation does restrain such efforts and necessitates great selectivity in the types of information collected.

The representative from the National Advisory Council for Nursing Research stated that baseline data on training for nursing, dentistry, and veterinary science needed to be developed so that accurate projections for future needs could be made.

In concluding deliberations on the recommendations, Dr. Raub expressed appreciation for the valuable refinements proposed by Advisory Committee members and Council representatives. He further indicated that NIH staff would appropriately convey the concerns of the Committee members and Council representatives about the difficulties caused by the tradeoffs related to aspects of the current funding climate.

A 5-Year Research Strategy

Initiation of a 5-Year Research Strategy

Dr. Raub introduced for consideration a proposal for the development of a 5-year research strategy for NIH. He prefaced his remarks by noting the statement of the Secretary of DHHS that strengthening biomedical research is an explicit goal of the Department. Although the fact that research is central to DHHS efforts has been recognized by a succession of Secretaries, it has rarely appeared in the larger context of the issues to be addressed by the Department. The Secretary's stance has also been echoed by the Assistant Secretary for Health, who has called for bold and multiyear thinking.

After noting that the need to increase the number of research project grants emerges first in any consideration of long-term objectives for NIH, Dr. Raub summarized the negative impacts of the current low award rate including the outstanding projects that go unfunded, the migration of individuals out of research, the secondary effects on students observing their mentor's plight, and the frustration of peer reviewers. There have also been increased attacks on the peer review system itself and on the decisionmaking approach of the Councils. Some of the unhappiness with the genome project has been rooted in the belief that the money might be spent more productively on project grants. However, Dr. Raub maintained that, as important as the project grant system is, the growth of project grants must be accompanied by a complementary growth of other NIH mechanisms if NIH's desired orientation and balance is to be maintained. Further, to advocate a larger investment in NIH, expected outcomes must be expressed in a number of ways. They must be tied to crosscutting scientific issues affecting all Institutes; to health status indicators and the health status of minorities and other underrepresented groups; to the impact on the economy, particularly the pharmaceutical and biotechnological industries; and to the impact on the research milieu itself.

After this introduction, Dr. Moskowitz discussed the underlying rationale for the 5-year research strategy. One aspect of the rationale is the impact of scientific discovery. Scientific discoveries are leading to a better understanding of basic mechanisms of living organisms and diseases, a process that must continue. Momentum in the transfer of this information to clinical medicine must also be sustained. Fiscal pressures and priority-setting issues are other aspects of the underlying rationale. The extensive investment of public funds in biomedical research necessitates basing funding decisions on judicious long-range plans. Moreover, the increasingly capital-intensive nature of biomedical research necessitates clearer priorities within and across research fields. The balance of basic to applied research must also be justified. Further, issues related to congressional policymaking are also relevant to the initiative's rationale. It must be demonstrated that

biomedical research is a cost-effective strategic resource. A comprehensive research plan will also provide a framework for the development of new policy initiatives relevant to biomedical research, technology transfer, and improvement of public health. Finally, the rationale includes the significance of the planning initiative to NIH and the ICD's. The initiative will establish an NIH-wide framework around which a variety of research support mechanisms could be planned. It would also serve as an "umbrella plan" to further promote the efforts of the individual ICD's to support significant biomedical research.

Dr. Moskowitz then outlined the proposed steps to initiate the 5-year planning strategy. A panel of expert consultants, perhaps including economists and an ethicist, would be established to cover a variety of biomedical research areas. The panel's mandate would be to identify crosscutting biomedical research themes and directions; the current knowledge base, promising research options, and scientific opportunities; gaps within research themes and directions; and conditions under which opportunities could be pursued and gaps addressed. The panel would also be asked to note active growth points within particular subfields and to determine if the current dynamics of knowledge development ensure significant advances in those fields. The impact of scientific progress and discovery on mortality, morbidity, and quality of life; potential costs and health benefits; and resource requirements would also be identified. After a series of meetings, the panel would report the results of its deliberations and its recommendations at the December ACD meeting. Ultimately, the report would be sent to the Department for clearance and then to the appropriate congressional committees.

Discussion

During discussion of the presentations on the 5-year research strategy, it was emphasized that to achieve the goals of the planning initiative within the brief timeframe proposed, the effort would have to be integrated and coordinated with related activities of other outside organizations such as the NAS.

Council representatives and Committee members reacted favorably to the planned initiative. It was suggested that it should be promoted to increase its visibility outside the health research field and as a means of providing information to the general public, Congress, and the executive branch. The discussion concluded with a request by Dr. Moskowitz for written recommendations from Council representatives and the Advisory Committee on potential expert consultants and themes to be addressed by the panel.

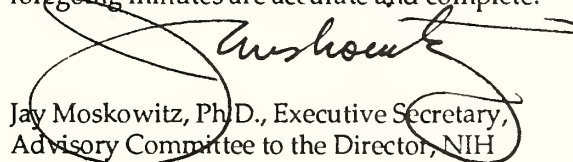
Closing Remarks

In his closing remarks, Dr. Raub thanked the Committee members and Council representatives for their contributions to a productive meeting and expressed appreciation for their time and energy.

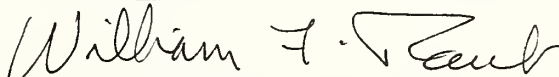
Summary and Conclusions

The Advisory Committee to the Director, NIH, with representatives of the National Advisory Councils and Boards of the NIH Institutes, met on June 1 to consider the report and recommendations of the NIH Task Forces for the Review of the NIH Biomedical Research Training Programs and to consider a new NIH effort to initiate a 5-year research strategy at NIH. After receiving status reports on activities related to continued progress in the administration of medical rehabilitation research at NIH and to strengthening the scientific review procedures of the NIH intramural research program, the focus turned to the principal purpose of the meeting, a consideration of the recommendations of the NIH Task Forces for the Review of the NIH Biomedical Research Training Programs. Presentations were heard on the broader context of research training from representatives of organizations concerned with research and higher education. The recommendations of the Task Forces on Physician Scientist Training, Training Opportunities in Clinical and Community-Based Designs and Methodology, and Predoctoral and Postdoctoral Training of Nonphysician Scientists, and the activities undertaken to implement Task Force recommendations were also summarized. While Advisory Committee members and Council representatives agreed with most of the recommendations made by the task forces, refinements in the language of the three recommendations dealing with length of training and the payback requirement were urged to ensure flexibility in implementing these recommendations. Committee members also believed that the recommendation for support of training in the areas of epidemiology and biostatistics required further internal attention as it relates to persons other than M.D.'s. No consensus was achieved on the recommendation for a two-tier cost of education allowance. Throughout these deliberations, Committee members repeatedly demonstrated great concern about the negative impact the current fiscal climate was having on NIH training activities and on the biomedical research enterprise as a whole. The second portion of the meeting focused on a new NIH effort to initiate a 5-year research strategy at NIH. Council representatives and Committee members reacted favorably to the planned initiative.

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.



Jay Moskowitz, Ph.D., Executive Secretary,
Advisory Committee to the Director, NIH



William F. Raub, Ph.D., Chairman,
Advisory Committee to the Director, NIH

Agenda

AGENDA

61st Meeting of the Advisory Committee to the Director National Institutes of Health

Review of the National Institutes of Health Biomedical Research Training Programs

Friday, June 1, 1990

*Building 31C, Conference Room 10
National Institutes of Health
Bethesda, Maryland*

- 8:30 a.m. Opening Remarks Dr. William Raub
- Status Report on Activities Following the 60th Meeting of the Advisory Committee to the Director
 - Introduction of the Subject of the Meeting.

I. RESEARCH TRAINING PROGRAM

- 9:00 a.m. Institute of Medicine Report on Manpower Dr. Joe G. Baker
- 9:20 a.m. Discussion
- 9:30 a.m. Study of M.D./Ph.D. Training Dr. Paul Jolly
- 9:50 a.m. Discussion
- 10:00 a.m. Report of the Association of American Universities
"The Ph.D. Shortage: The Federal Role" Dr. Robert Rosenzweig
- 10:20 a.m. Discussion
- 10:30 a.m. Coffee Break
- 10:50 a.m. Physician Scientist Training Dr. Jay Moskowitz
- 11:10 a.m. Training in Clinical and Community-Based
Study Designs and Methodology Dr. Curtis Meinert

- 11:30 a.m. Predoctoral and Postdoctoral Training of
Nonphysician Scientists Dr. Ruth Kirschstein
- 11:50 a.m. Discussion
- 12:15 p.m. Lunch
- 1:30 p.m. Report of Activities to Implement
Recommendations Contained in Report Dr. George Galasso
- 1:50 p.m. Discussion Mr. Rodney Nichols
(Discussion Leader)

II. THE 5-YEAR RESEARCH STRATEGY

- 3:00 p.m. Initiation of a 5-Year Research Strategy Dr. William Raub
Dr. Jay Moskowitz
- 3:40 p.m. Discussion
- 4:00 p.m. Closing Remarks Dr. William Raub

**Advisory Committee to the Director,
National Institutes of Health**

Advisory Committee to the Director, NIH

May 1990

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Advisory Council and Board Representatives

June 1, 1990

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June 1, 1990

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Report of the Task Forces for the Review of NIH Biomedical Research Training Programs

**Review of the National Institutes of Health
Biomedical Research Training Programs**

October 1989

FOREWORD

The Steering Committee is pleased to present this report on behalf of the three Task Forces established to review the biomedical research training programs of the National Institutes of Health (NIH).

Since their establishment in April 1989, the three Task Forces have been engaged, respectively, in review of traditional biomedical science-based training programs for physician scientists; development of an approach to train physicians and others in areas not being addressed adequately, e.g., epidemiology, biostatistics, and demography; and examination of the traditional predoctoral and postdoctoral training programs for nonphysician scientists. Members of the Task Forces want to express appreciation to those members of the scientific community and NIH staff who provided comments and resource information. Their efforts contributed substantially to this review. Appreciation is also expressed to Dr. Barbara Packard who served as rapporteur for this report.

The Steering Committee and members of the Task Forces are hopeful that this report will provide a framework for a productive research training effort and the preparation of biomedical scientists whose work will ensure the future success of the NIH mission.

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Dr. Ruth L. Kirschstein
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Dr. Carl Kupfer
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EXECUTIVE SUMMARY

In April 1989, Dr. James Wyngaarden, Director, National Institutes of Health (NIH), established three Task Forces to review NIH biomedical research training programs in terms of:

Traditional biomedical science-based training programs to develop physician scientists.

Areas of research training not currently addressed adequately or systematically, e.g., clinical trial design and methodology, biostatistics, epidemiology, and population demography.

Traditional predoctoral and postdoctoral training programs for nonphysician scientists.

The Task Forces met separately to consider issues related to their individual charges and to develop recommendations. A Steering Committee, consisting of the chairs of each Task Force, was established to integrate the outcomes of the Task Forces. This report represents the deliberations, conclusions, and recommendations of the three Task Forces. A total of seven major issues were identified and addressed during the review of the NIH biomedical research training programs:

Early recruitment of talented individuals into biomedical research careers.

Optimal structure of postdoctoral research training for professional doctorates.

Integration of research training with clinical certification requirements and the relationship of research training to clinical training.

New approaches and opportunities for research training.

Trainee stipends and cost of education.

K-series awards.

Data collection, monitoring, and evaluation.

Major conclusions and recommendations are summarized below.

Early Recruitment of Talented Individuals Into Biomedical Research Careers

Currently, inadequate numbers of individuals with professional doctorates are entering biomedical research careers. Studies of existing short-term training programs for health professional students suggest that such programs are effective in stimulating interest in research careers. Early recruitment efforts will be enhanced by providing opportunities for predoctoral research experiences as part of institutional training grant programs.

RECOMMENDATION

PROFESSIONAL PREDOCTORAL STUDENTS SHOULD BE ELIGIBLE FOR TRAINING ON INSTITUTIONAL TRAINING GRANTS DURING THE SUMMER OR ELECTIVE TIME FOR PERIODS OF BETWEEN THREE AND 12 MONTHS WITH A MAXIMUM OF 12 MONTHS. A MINIMUM OF SIX MONTHS SHOULD BE ENCOURAGED.

Optimal Structure for Postdoctoral Research Training

The objective of the National Research Service Award (NRSA) training programs is preparation of independent, productive researchers. A strong relationship exists between the duration of postdoctoral research training and subsequent success in receiving NIH independent research support. Research training for periods of 12 months or less is inadequate to prepare professional doctorates for successful research careers. It was concluded that, in most cases, postdoctoral research training for professional doctorate recipients should extend for a period of up to five years.

A limited commitment on the part of professional doctorate trainees and a lack of selectivity on the part of the training director may be two factors that result in ineffective institutional training grants. Revision of the payback requirement, coupled with a two-year minimum requirement for professional doctorate recipients appointed to training grants, should result in recruitment of trainees with increased commitment. Rigorous review of training program success in retaining individuals through completion of their initial training commitment will improve selectivity by training directors.

Applications for institutional NRSA grants need to include information in a standardized, tabular form in order to evaluate performance and possibly expedite review.

No apparent relationship exists between training grant size and trainee success, but review will ensure that the requested number of trainees is consistent with individual BID policies and the training institution's resources and ability to provide appropriate preceptors. Review also will consider the apparent advantage of grant applications that propose training both professional doctorates and academic doctorates in the same program. Special training experiences at institutions other than parent training institutions may be beneficial in certain cases, but provision for the training must be included in the grant application or subsequently approved by NIH staff.

RECOMMENDATION

A MINIMUM OF TWO YEARS OF TRAINING SHOULD BE REQUIRED FOR ALL PROFESSIONAL DOCTORATE APPOINTEES TO INSTITUTIONAL NRSA GRANTS. TRAINEES SHOULD BE ENCOURAGED TO APPLY FOR FURTHER RESEARCH TRAINING AND CAREER DEVELOPMENT THROUGH NATIONAL COMPETITION. TRAINING GRANT APPOINTMENTS MAY BE

EXTENDED BEYOND TWO YEARS UPON THE RECOMMENDATION OF THE TRAINING DIRECTOR AND WITH THE CONCURRENCE OF THE NIH.

THE NIH/DHHS SHOULD PLAN FOR MODIFICATION OF THE PAYBACK REQUIREMENT OF THE NRSA REAUTHORIZATION LEGISLATION.

REVIEW OF COMPETING RENEWALS FOR NRSA TRAINING GRANTS SHOULD FOCUS UPON PERFORMANCE, IN TERMS OF THE PREPARATION OF TRAINEES FOR PRODUCTIVE RESEARCH CAREERS.

NUMBERS OF TRAINEES IN TRAINING PROGRAMS SHOULD BE CONSISTENT WITH INDIVIDUAL BID POLICIES AND THE INSTITUTION'S RESOURCES.

THE PRESENCE OF BOTH M.D. AND PH.D. TRAINEES IN THE SAME PROGRAM SHOULD BE CONSIDERED FAVORABLY IN THE REVIEW OF NRSA TRAINING GRANT APPLICATIONS.

SPECIAL TRAINING EXPERIENCES AWAY FROM THE TRAINING INSTITUTION MAY BE PROPOSED AS PART OF THE TRAINING GRANT APPLICATION OR SUBSEQUENTLY TO NIH STAFF.

Integration of Research Training With Clinical Certification Requirements and the Relationship of Research Training to Clinical Training

The revised research training structure can be effectively integrated with the requirements for clinical training. The existing investigator track for board certification permits research training and satisfies the requirements for both board certification in internal medicine and subspecialty certification within the normal clinical training period. Differing approaches to integrating research training with clinical training are likely to exist, and they can be permitted as long as NRSA training grant appointments are not used to support clinical training.

RECOMMENDATION

MULTIPLE PATHWAYS SHOULD BE PERMITTED TO ACCOMMODATE THE NEEDS FOR CLINICAL CERTIFICATION WITHIN THE CONTEXT OF THE RESEARCH TRAINING EXPERIENCE OF TWO OR MORE YEARS.

New Approaches and Opportunities For Research Training

Expanded opportunities for research training and research career development are required to meet the demand for individuals capable of designing, implementing, and analyzing epidemiologic studies and clinical trials, as well as for individual experts in biostatistics.

Individual predoctoral fellowships are currently being used effectively within the Public Health Service. These fellowships may have potential

to complement NIH predoctoral training grants by increasing the number of institutions available for training. Such possibilities demonstrate the need for periodic reviews of the relevance of existing training programs to the current and future needs of the sponsoring BIDs. New programs should be initiated and old programs discontinued as appropriate.

RECOMMENDATION

ADVANCED PROGRAMS OF STUDY AND K-SERIES AWARDS SHOULD BE SUPPORTED IN EPIDEMIOLOGY, BIOSTATISTICS, OR RELATED TOPICS TO INCREASE PREDOCTORAL AND POSTDOCTORAL RESEARCH TRAINING OPPORTUNITIES. CURRENT NIH MECHANISMS ALSO SHOULD BE USED TO SUPPORT MASTER'S DEGREE-LEVEL PROGRAMS AND NONDEGREE CERTIFICATE PROGRAMS THAT FOCUS ON THESE TOPICS.

THE OPPORTUNITY FOR INDIVIDUAL PREDOCTORAL FELLOWSHIPS TO ADDRESS SPECIFIC NIH TRAINING NEEDS SHOULD BE REVIEWED.

NEEDS IN NEW RESEARCH AREAS AND APPROACHES FOR NIH RESEARCH TRAINING TO RESPOND TO THESE NEEDS SHOULD BE EVALUATED ON AN ONGOING BASIS.

Trainee Stipends and Cost of Education

Current NRSA stipend levels are below salaries paid to housestaff with comparable years of postgraduate experience. Consequently, individuals who elect to pursue research training are forced to accept a reduced salary. The NRSA stipend structure can be revised so that it provides an incentive for recipients of professional doctorates interested in research careers. Increased stipend levels also are needed for predoctoral and postdoctoral nonphysician scientist trainees.

Inclusion of some support for the cost of education is appropriate in institutional research training grants. However, with constantly rising tuition charges, declining NIH research training budgets in terms of constant dollars, and decreases in the number of predoctoral trainees, the NIH must seek approaches to stabilize the situation. A "two-tier cost of education (CoE) allowance" for predoctoral training, i.e., one level for private institutions and another for public institutions, would control the portion of the NIH training budget allocated to educational expenses. The annual decision regarding the CoE allowance can be made with the objective of maintaining at least a constant number of trainees. These two-tier CoE levels are also applicable to special NIH training programs.

The mechanism for research training support should be made more comparable across Federal agencies.

RECOMMENDATION

POSTDOCTORAL STIPENDS FOR PROFESSIONAL DOCTORATES SHOULD BE AT LEAST AS ATTRACTIVE AS CURRENT HOUSESTAFF SALARIES. STIPEND LEVELS ALSO SHOULD BE INCREASED FOR ACADEMIC TRAINEES. ANNUAL STIPEND INCREASES ARE NECESSARY TO COMPENSATE FOR INCREASED LIVING COSTS.

THE PROPOSED "TWO-TIER COST OF EDUCATION ALLOWANCE" AS A MECHANISM TO LIMIT TUITION PAYMENTS IS REAFFIRMED. THE SAME GENERAL PRINCIPLES SHOULD BE APPLIED TO SPECIAL NIH RESEARCH TRAINING PROGRAMS.

FEDERAL AGENCIES SUPPORTING BIOMEDICAL RESEARCH TRAINING SHOULD EXPLORE WAYS OF MAKING THEIR SUPPORT MECHANISMS MORE EQUIVALENT.

K-Series Awards

A full five years of career development support may be more than is needed for all individuals who have completed the two or more year appointment on a research training grant. A three-year career development award, when coupled with the two-year training experience, would provide professional doctorates with the total of five or more years of research experience deemed necessary to prepare them for a successful research career.

Salaries for K-series awards should be higher than corresponding stipends for training grant appointments. In this way, trainees will be offered a further incentive to seek independent support through national competition.

RECOMMENDATION

THREE-YEAR K-SERIES AWARDS SHOULD BE MADE AVAILABLE FOR PROFESSIONAL DOCTORATES. SALARIES SHOULD BE INCREASED TO \$50,000 PER YEAR ON K-SERIES AWARDS.

Data Collection, Monitoring, and Evaluation

Regular reviews and analyses are necessary to determine the effectiveness of the NRSA training programs. A number of data sources are available to the NIH that offer opportunities for important insights into program performance. At present, they are not explored to the fullest extent possible. Collecting additional data will permit a more complete assessment of NIH training activities.

RECOMMENDATION

STANDARDIZED INFORMATION NECESSARY TO ASSESS PROGRAM PERFORMANCE SHOULD BE COLLECTED ON ALL INDIVIDUALS AND INSTITUTIONS RECEIVING NRSA RESEARCH TRAINING SUPPORT.

AVAILABLE NIH TRAINING DATA SHOULD BE ANALYZED FURTHER AND NEW DATABASES ESTABLISHED AS NEEDED.

I. BACKGROUND

A. Overview

The contribution of research training to the development of productive researchers and the advancement of biomedical science is widely recognized. Continued research progress can be ensured only if adequate numbers of appropriately trained individuals pursue careers in biomedical research.

On April 19, 1989, Dr. James B. Wyngaarden, Director, National Institutes of Health (NIH), reemphasized the importance of research training to the mission of the NIH by establishing three Task Forces to review the NIH biomedical research training programs, identify and assess issues, and make recommendations for improvements. He requested that the Task Forces complete their review so that implementation of recommendations could begin with the next major application cycle, i.e., January 1990. He asked them to focus upon:

Traditional biomedical science-based training programs to develop physician scientists.

Areas of research training not currently addressed adequately or systematically, e.g., clinical trial design and methodology, biostatistics, epidemiology, and demography.

Traditional predoctoral and postdoctoral training programs for nonphysician scientists.

The NIH training program currently consists of a series of mechanisms of support, including the institutional training grant (T-series) and the individual fellowship award (F-series) supported through National Research Service Award (NRSA) funds, and the career development awards (K-series) supported through research project grants. While most trainees are supported initially on a training grant, individual fellowship grants are available at any stage of research training. Further development of research skills is supported through the career development awards. Individuals with advanced research experience may compete, at any time, for independent research support through either a First Independent Research Support and Transition (FIRST) award (R29) or a research project grant (R01) award.

This report is based on the deliberations of the three NIH Task Forces.

B. Task Force Procedures

1. Task Force on Physician Scientist Training

The Task Force was convened in May 1989, and charged with the responsibility to review the NIH training programs for physician

scientists and make recommendations for their improvement. A number of indicators suggest that improvements are, in fact, needed:

The percentage of M.D. trainees who subsequently apply for and receive NIH research grants is unacceptably low.

More than 60 percent of M.D.s are trained for 12 months or less. NIH data indicate that those who are trained for longer periods are more successful in competing for NIH support.

Postdoctoral positions on training grants are sometimes used to support individuals other than those committed to a career in biomedical research.

Some training grants have not been effective in producing physician scientists.

During its review of NIH training programs for physician scientists, the Task Force was asked to consider the following questions about the current training grant program:

Is the training grant still the best way to introduce physicians to research?

Should it be modified . . . or perhaps phased into a K-series . . . award to provide an adequate continuum of training?

Are there ways to make the current NIH research training program more effective?

Should the training grants be phased out for physician scientists or reduced in favor of the K-series approach?

The Task Force met eight times between May and August 1989. Dr. Wyngaarden met with members in May to deliver the formal charge and discuss several aspects of the topic with them. Over the course of their meetings, the members considered a number of issues, including:

Early recruitment of talented individuals into biomedical research careers.

Optimal structure of postdoctoral research training for professional doctorates.*

Integration of research training with clinical certification requirements and the relationship of research training to clinical training.

Trainee stipends.

K-series awards for professional postdoctoral candidates.

* The Task Force designated the term "professional doctorates" to encompass other relevant professional degrees as well as M.D.s.

Background data were provided to the Task Force on these issues. In addition, discussion papers were prepared for review on (1) the structure and nature of an optimal research training program for professional doctorates, (2) a revised K-series award, (3) trainee stipends, and (4) the training grant application process and review criteria.

The Task Force shared its ideas with:

The National Heart, Lung, and Blood Advisory Council (NHLBAC).

The National Institute of Arthritis and Musculoskeletal and Skin Diseases Advisory Council (NIAMSAC).

In order to receive the broadest range of consultation, the Task Force members also invited the following individuals to meet with them:

Dr. John A. Oates, Jr.
Chairman, Department of Medicine
Vanderbilt University
Member, NHLBAC

Dr. William Hazzard
Chairman, Department of Medicine
Bowman Gray School of Medicine
Member, American Board of Internal Medicine (ABIM)

Dr. Arthur Nienhuis
Chief, Clinical Hematology Branch, NHLBI
Member, ABIM

In addition, several letters were received from members of the scientific community, organizations, and NIH staff, who shared their views on the research training of professional doctorates with the Task Force.

2. Task Force on Training Opportunities in Clinical and Community-Based Study Designs and Methodology

The Task Force was convened on June 19, 1989, and Dr. Wyngaarden delivered the formal charge to develop an approach to train physicians and others in areas that are not being addressed adequately or systematically, e.g., clinical trial design and methodology, biostatistics, epidemiology, and demography. Members subsequently discussed features of advanced programs for research training and career development in epidemiology, biostatistics, or related topics as well as additional programs for health professionals. The Task Force also considered issues of eligibility and mechanisms of support. A draft Task Force report was reviewed at a second meeting on June 29, 1989. Thereafter, the Task Force used mail review to develop and complete an interim report for the Director, NIH, and for consideration at the July 27, 1989, meeting of BID Directors.

3. Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists

The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists met six times. At its first meeting on May 23, 1989, Dr. Wyngaarden charged members to examine traditional predoctoral and postdoctoral training programs for nonphysician scientists. He indicated that the outcomes for nonphysician scientists who previously had NIH research training support were good.

A number of important issues were identified for consideration, including:

- Data collection and evaluation studies.

- Problems regarding tuition and stipends.

- New approaches, opportunities, and needs for research training.

Working groups of the Task Force were established and each was assigned one of these topics. The full Task Force reviewed and modified draft reports from the working groups. A preliminary report, including a series of recommendations, was prepared and submitted for consideration by the Director, NIH, and the BID Directors.

C. History of NIH Research Training Programs

1. Early Training Authorities and Activities

The initial legislation that authorized the NIH to conduct and support training was provided in 1930 by the Ransdell Act (P.L. 71-251), the same legislation that formally established the then National Institute of Health. Thus, from its inception, the NIH has been directed to recognize training as one of its major responsibilities. Under the terms of the Ransdell Act, individual scientists could be designated "... to receive fellowships ... for duty in the National Institute of Health ..." or "... for the prosecution of investigations in other localities and institutions in this and other countries ..."

When Congress passed the National Cancer Act (P.L. 75-244) in 1937 and thereby established the first of the disease-specific institutes, it included in the legislation a provision for training in cancer. This provision led to the first major fellowship program supported by the U.S. Government. According to terms of the Act, research fellowships established under it were to provide "... such stipends or allowances ... as the Surgeon General may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States or abroad ...". Because the National Cancer Act also authorized "... training and instruction in technical matters relating to the diagnosis and treatment of cancer ...", the National Cancer Institute (NCI) focused its initial training efforts on postdoctoral research fellows and

clinical training for physicians to improve their capability in diagnosis and therapy. Awards for both kinds of training were made to individuals selected by NCI staff.

In 1946, the Public Health Service (PHS) Act provided explicit authority for grants for the support of training, and this authority was extended and expanded in the National Heart Act (P.L. 80-655) of 1948. The text of the National Heart Act specifically provided for the possibility of grants for training programs. It permitted the new National Heart Institute to:

“ . . . establish and maintain traineeships, in the Institute and elsewhere in matters relating to the diagnosis, prevention, and treatment of heart disease . . . the number of persons receiving such training and instruction, and the number of persons holding such traineeships, to be fixed by the Council, and in addition, provide for such training, instruction, and traineeships through grants”

Also, in 1948, the National Dental Research Act (P.L. 80-755) followed the pattern of authority for training set forth in the National Heart Act. The PHS Act amendments (P.L. 81-692) of 1950, which established the National Institute of Arthritis and Metabolic Diseases and the National Institute of Neurological Diseases and Blindness, provided very broad training authorities for the new Institutes and extended those authorities to all existing Institutes. Subsequent legislation establishing additional Institutes all contain comparably broad training authority.

The first departure from a system of awards to individuals occurred in 1948 with the initiation of undergraduate training grants. These training grants were made to professional schools to strengthen their undergraduate teaching capabilities in selected fields. The grants provided the same amount for each institution of a given type. They included no stipends for individuals but instead, provided funds for use at the recipient school's discretion to purchase equipment, acquire instructional material, and offer faculty salary support.

2. Changes in NIH Training Programs

Significant changes have occurred in NIH training programs since the 1930 passage of the Ransdell Act. The training grant mechanism was modified by the National Heart Institute in 1950 to provide support for graduate-level training and include funds for training stipends. In addition, the new graduate-level training grant differed from its undergraduate predecessor in that the award amounts varied from one institution to another. A further differentiation between the graduate and undergraduate training grant was subsequently introduced. Grantee institutions were permitted increased latitude in the management of the graduate grants; they were allowed to select trainees without prior central NIH review and to set the level of individual stipends. With these modifications, the basic pattern of the institutional training grant was developed.

An important change occurred in 1954, when part-time fellowships, usually for summer work, were initiated to stimulate the interest of medical and dental students in research and permit early identification of talent. Later in 1957, a program was established that permitted medical and dental students to spend a year in research between their preclinical and clinical years. It was also about this time that some training programs began to focus on the needs of faculty and research. Gradually, the use of clinical traineeships was phased out. The Division of Research Grants provided the initial NIH focus for support of research training in fundamental disciplines related to health, e.g., biophysics, epidemiology, and biostatistics. In 1958, these training grants and predoctoral training programs from the established Institutes were transferred to the Division of General Medical Sciences, now the National Institute of General Medical Sciences.

These developments, as well as a growing demand for scientists and teachers, an adequate pool of potential trainees, and expansion of the biomedical research effort, led to rapid expansion of NIH training programs in the late 1950s and early 1960s. The number of trainees supported by NIH under its original training authority reached over 16,000 in 1969. By 1971, NIH training grants and fellowships supported or assisted 37.5 percent of the nation's full-time graduate students in the medical sciences and 21 percent in the life sciences. However, in its presentation of the fiscal year (FY) 1974 budget, the Administration made an attempt to eliminate the award of all new training and fellowship grants.

Congress responded by providing new authority with the National Research Service Award Act of 1974 (Title I, P.L. 93-348). This Act abolished all previous training authorities under the PHS Act and consolidated them under the National Research Service Award (NRSA). It provided both predoctoral and postdoctoral support to individuals and additional support to institutions training such individuals. It also provided for a payback requirement* as a condition of receiving support. This provision was intended to discourage the use of this authority to support clinical training of physicians. In implementing the provisions of the NRSA, the NIH established individual postdoctoral fellowships (F32s) and institutional training grants for predoctoral and postdoctoral students (T32s).

During the 1970s, there was a decline in the number of trainees. For the first few years following passage of the NRSA legislation, NIH research trainees were supported by a combination of remaining commitments under the old training authority and the new NRSA authorizations.

* For each year of NRSA support, recipients were required either to serve for an equivalent period of time in research, teaching, or providing medical care to an underserved area or to reimburse the government for the cost of the training.

Since 1979, the number of full-time research training positions budgeted for the NIH under the NRSA has been relatively stable, fluctuating between a high of \$11,197 in 1979 and a low of \$10,382 in 1986. The number of physicians was 11,181 in 1987.

The programmatic evolution of training grants was gradual across the NIH, and emphasis was individualized depending on the particular fields of science needed to carry out the mission of a Bureau, Institute, and/or Division (BID). The versatility and flexibility of the training grant made it an ideal vehicle for this effort.

The fundamental goal of the NIH research training programs is to prepare well-trained, highly qualified, and productive research investigators in fields relevant to the advance of biomedical science. The NRSA is the only current authority under which the NIH supports basic preparation of individuals for careers in biomedical research. Through a system of institutional training grants and individual fellowships, the trainee or fellow receives a stipend for full-time concentrated study and may elect, under supervision, an individual research focus. Funds are awarded for predoctoral and postdoctoral stipends, and for tuition where warranted, with a modest allocation to the institution to defray training-related expenses not covered by tuition.

II. DISCUSSION AND RECOMMENDATIONS

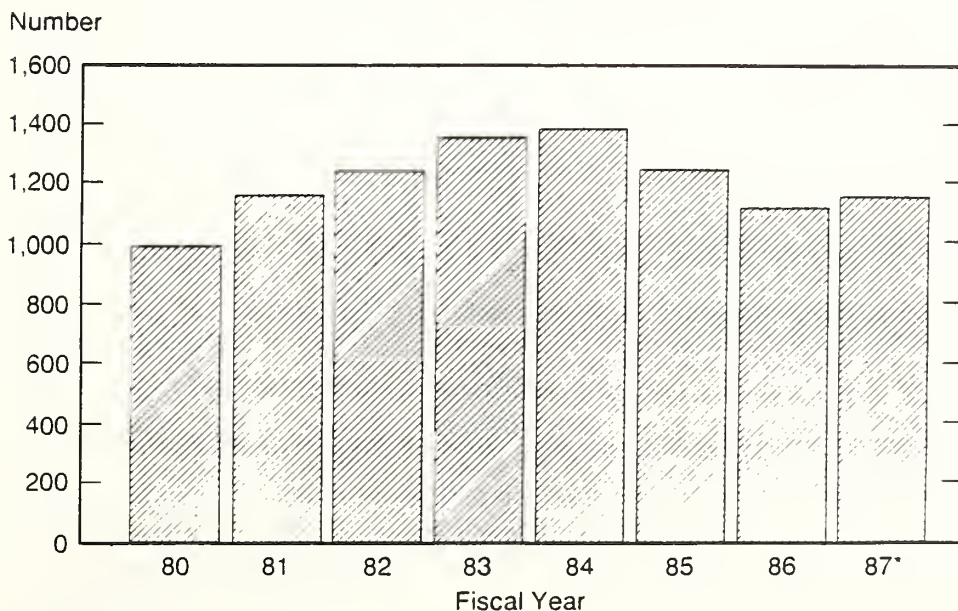
A. Early Recruitment of Talented Individuals Into Biomedical Research Careers

1. Current NIH Programs

The Task Force on Physician Scientist Training is concerned that inadequate numbers of individuals with M.D.s or other professional doctorates are entering into research careers. A study of the impact of the short-term training program for health professional students (T35) showed that program participants were twice as likely to express an interest in a research career at the time of graduation as were individuals who did not have the benefit of such an experience. Additionally, T35 trainees have research goals and demonstrate a relatively greater appreciation of the value of a basic science foundation preparatory to a research career. The NIH supported an estimated 1,156 appointments of individuals for short-term training in FY 1987 (Figure 1). Currently, the National Institute of Neurological Disorders and Stroke (NINDS) supports a limited number of short-term traineeships on its institutional NRSA training grants to provide professional predoctoral students with two or more "off-quarter" opportunities for involvement in research.

Such a program supported as part of the training grant may offer an effective mechanism for stimulating research interest among professional predoctoral students. It was agreed that both T35 and T32 training mechanisms are important training opportunities for professional predoctoral students and that both are needed.

Figure 1
Short-Term Research Training (T35s)
Number of Appointments



* Estimated

Source: NIH Data Book 1988

2. Early Recruitment Opportunity for Training Grants

The intent of the training program for professional predoctoral students is to provide opportunities for participation in biomedical research training over the course of, but prior to the completion of, professional doctorate training. The incorporation of training of professional predoctoral students into the institutional training grant offers several advantages. It introduces individuals, at an early stage of their professional training, to the concept of a continuum of research training and career development. The faculty of the training grant is available to the participating students, and the training director is expected to report on progress and success of the training. Students can become predoctoral trainees on training grants either at the institution from which the degree will be conferred or at another institution. Additionally, a participant in the predoctoral program can continue postdoctoral training on a training grant either at the institution from which the degree was conferred or at another one.

More opportunities, in addition to those currently available, are needed to stimulate interest in research careers among predoctoral students in health professional schools. Inclusion of professional predoctoral students on training grants will enhance efforts of early recruitment of talented individuals into biomedical research careers.

RECOMMENDATION

Eligibility for training on an institutional training grant should be extended to include professional predoctoral students, whose training would be in summer or elective time for periods of between three and 12 months with a maximum of 12 months. A minimum of six months should be encouraged.

B. Optimal Structure of Postdoctoral Research Training

1. Length of Training

Early in its deliberations, the Task Force on Physician Scientist Training addressed the issue of the length of research training required to prepare professionally trained individuals for independent research careers. Data were reviewed that showed a strong relationship between the duration of postdoctoral research training and subsequent success in receiving NIH independent research support. The preparation of independent, productive researchers is the underlying objective of the NRSA Training Program. An important measure of the level of research development of trainees is their likelihood of submitting applications for and receiving NIH research grant support. While the current NRSA program permits support for postdoctoral appointments of up to 36 months, NIH data show that more than 60 percent of professional doctorate degree recipients are appointed to training grants for a total of 12 months or less (Figure 2). Other data indicate that the percentage of

M.D. trainees who became NIH grant applicants and awardees has been decreasing since FY 1976.

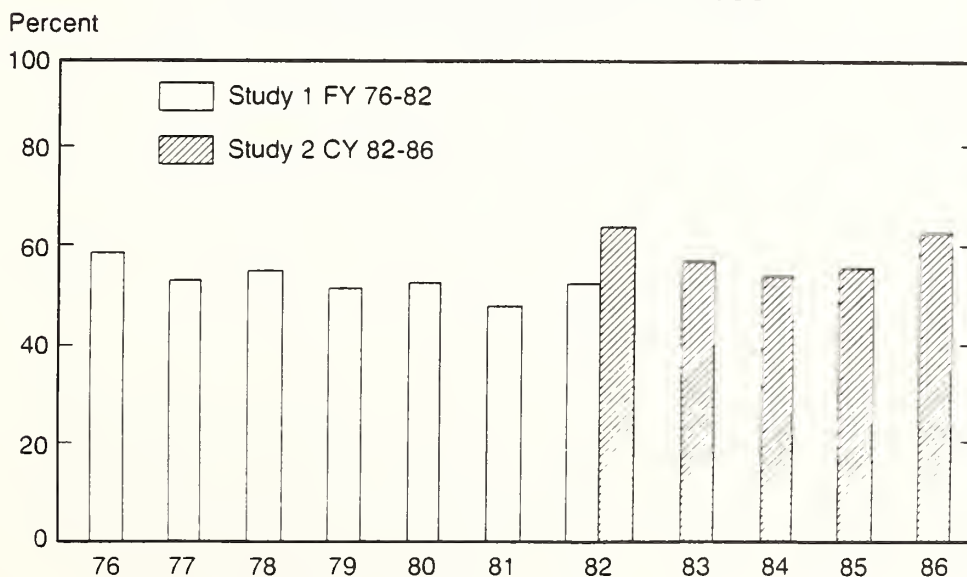
An analysis of professional postdoctoral trainees, FY 1976-1982, who subsequently became NIH grant applicants and awardees showed that the longer the period of training, the more likely an individual trainee is to apply for and receive NIH research grant support (Figure 3). The Task Force recognized that individuals may receive research training support from non-NIH sources. However, the fact remains that, overall, M.D.s have low NIH grant application and award rates.

The Task Force and all of its consultants were unanimous in concluding that 12 months of postdoctoral research training is inadequate to prepare most individuals for independent research careers and that training should, in most cases, extend for a period of up to five years. Members expressed enthusiasm and confidence in the institutional training grant as a mechanism of support. They would like to see it more effectively utilized, particularly for professional postdoctoral training.

2. Training Structure

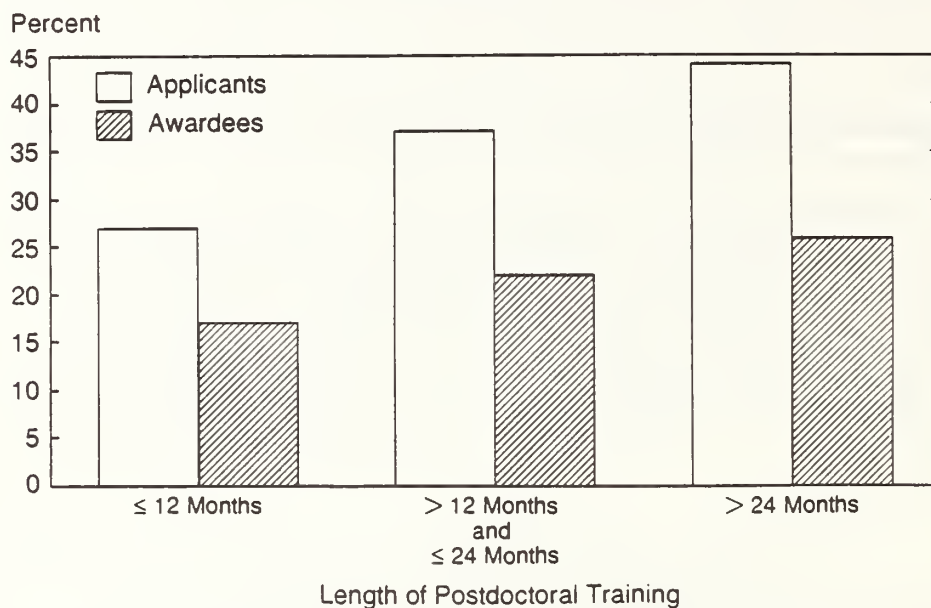
The apparent ineffectiveness of a number of training grants in producing physician scientists focused attention upon the role of institutional training grants in a redesigned research training structure. The lack of success of some training programs may be due to a limited commitment to research on the part of the trainees and to a lack of selectivity on the part of the training directors.

Figure 2
Postdoctoral MD Trainees
Who Trained 12 Months or Less



FY: Fiscal year
CY: Calendar year
Source: NIH, OD-OSPL

Figure 3
Postdoctoral MD Trainees Who Became
NIH Grant Applicants and Awardees
FY 76 to 82



The requirement of a minimum of two years of research training and the modification of the NRSA payback requirement will serve to increase commitment on the part of trainees. With a minimum appointment period of two years instead of nine months, only individuals with a real interest in research careers will be likely to accept appointments. Incentive to complete the minimum appointment period would be provided by modifying the payback requirement so that it is incurred by the first year of training and satisfied by successful completion of the second year. It was recognized that the proposed modification to the payback requirement will need legislative action. The payback requirement also will need to be changed for the first year of an individual fellowship grant award (F32) to reflect the corresponding change for training grant awards. The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists believes that the payback provisions for such individuals also should be reconsidered. In view of the proposed modification of the payback requirements for trainees who are holders of professional doctorate degrees and the need for legislation to make such a change, NIH should develop an overall plan that addresses the entire payback requirement.

The need for research training opportunities extending beyond the first two years of training was considered. It was decided to allow optional appointments for a third or, in exceptional circumstances, fourth year on a training grant. While it was readily agreed that training directors should still be permitted to select individuals for research training, there was a concern about the appropriateness of delegating to them the decision to extend support to a trainee beyond the first two years.

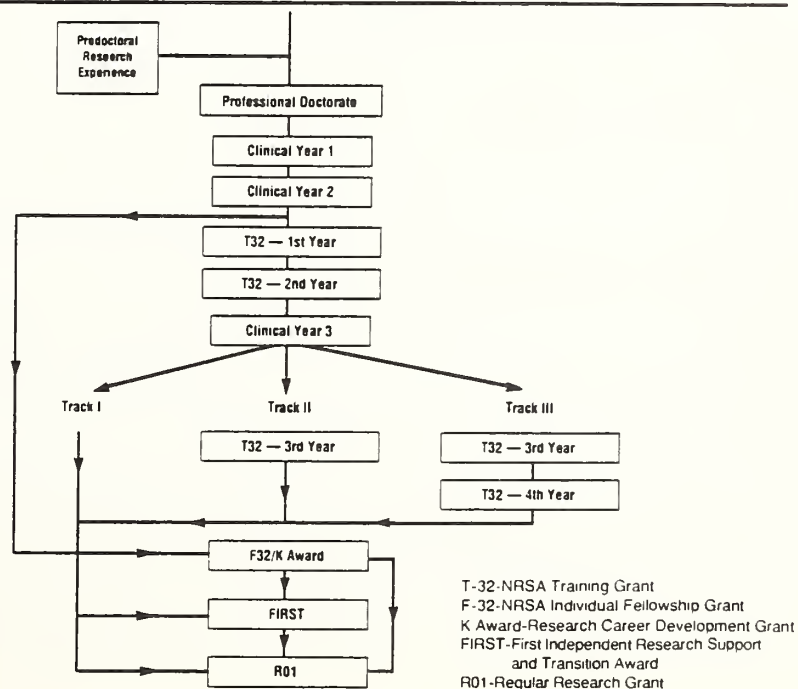
However, it was recognized that a rigorous review of the success of training programs in preparing individuals for independent research careers, when coupled with an NIH review of appointments for a third or, in exceptional cases, a fourth year of training, could be effective in ensuring that such appointments are appropriate. The proposal for a revised research training grant program for professional doctorates is illustrated in Figure 4. Multiple pathways are possible.

Improved selectivity by training directors can be ensured by rigorous review of training program success in retaining individuals through completion of the initial training commitment. Task Force members agreed that institutions should lose both training positions and funds for training positions filled by individuals who leave the program before completing their training experience. However, if a trainee receives an alternate award, such as an NIH individual fellowship or K-series award, or an equivalent award from non-NIH sources, a request for the balance of time and funds for the training position could be submitted to NIH staff for consideration.

3. Application and Review Procedures

Revised requirements for institutional NRSA training grant applications were developed by the Task Force. Applications will now be expected to convey aims that are consistent with the revised research training program and to describe how they will be addressed. In addition, certain information will be required in a standardized, tabular form to expedite review. The tables will include:

Figure 4
Research Training For Professional Doctorates



Current grant and contract research support and training support of the proposed training faculty.

Preceptor experience of present and proposed faculty supported by NRSA research training grants, NRSA fellowships, and by other means.

Research publications by trainees during the past five years.

Applications submitted and awards received by trainees for research support from NIH and other sources during the past five years, including those where they participated as a co-investigator.

Other support for training and current number of trainees of participating faculty.

In particular, trainee recruitment, selection, and activities will be described more fully and increased emphasis placed on the likelihood of the proposed program to achieve the stated aims on the basis of past record.

Revised review criteria include:

Past record of preceptors in research training.

Design and direction of the training program.

Caliber of preceptors.

Training environment, including attention to ethical standards of research.

Recruitment and selection plans for trainees, including underrepresented minorities and women.

Available training experiences and activities.

Career development plans and tracking process for trainees.

4. Other Aspects

Three other aspects of research training programs were addressed. It was agreed that arbitrary limits should not be placed by NIH upon the number of trainees permitted on a training grant since available data show no relationship between training program size and the subsequent development of trainees into independent researchers. Instead, the number of trainees should be consistent with individual BID policies and the institution's resources and its ability to provide appropriate preceptors. It also was agreed that the presence of both M.D. and Ph.D. trainees should be considered in the review of research training grant applications. Data indicate that M.D. trainees who are trained in programs that also train Ph.D.s are more likely to apply for and receive independent NIH research support than M.D. trainees who train only with other M.D.s. Finally, it was agreed that trainees could be allowed to spend up to one year in a training experience away from the parent

institution, with continued stipend support from the training grant. However, such a training experience could only be supported by a training grant if it was included either as part of the training grant application or subsequently approved by NIH staff.

RECOMMENDATION

The proposal for a revised training grant program includes a requirement for a minimum of two years of training for all appointees to institutional NRSA grants. After that time, trainees should be encouraged to apply for support for further research training (F32) and career development (K08, K11) through national competition. However, training grant appointments could be extended for an additional one or, in exceptional circumstances, two years upon the recommendation of the training director and with the concurrence of the NIH.

The NIH should develop a plan for appropriate modification of the payback requirement of the NRSA reauthorization legislation.

Review of competing renewals for NRSA training grants should focus upon performance. In particular, the review should consider the:

- Past record of preceptors in research training.

- Design and direction of the training program.

- Caliber of preceptors.

- Training environment, including attention to ethical standards of research.

- Recruitment and selection plans, including minorities and women.

- Available training experiences and activities.

- Career development plans and tracking process for trainees.

The presence of both M.D. and Ph.D. trainees in the same program should be considered favorably in the review of research training grant applications.

The number of trainees permitted on a training program should be consistent with individual BID policies and the institution's resources, including its ability to provide appropriate preceptors.

Individual trainees should be allowed up to one year of special training experiences at institutions other than the parent institution with continued stipend support from the training grant, if proposed as part of the training grant application.

C. Integration of Research Training With Clinical Certification Requirements and the Relationship of Research Training to Clinical Training

In developing the proposal for a revised research training structure, the Task Force on Physician Scientist Training focused first upon the extent and nature of training required to prepare recipients of professional doctorates for independent research careers. It was realized, however, that any revision to the existing training structure would have to be compatible with the requirements for board certification. Therefore, views of representatives of the scientific community who were familiar with the clinical training requirements for board certification were sought.

Based upon the information received, it appears that the revised research training structure can be effectively integrated with the requirements for clinical training. An accepted investigator track for board certification already exists that permits qualified individuals to credit two years of intensive research experience toward the training time required for board certification in internal medicine. As a consequence, an individual following the investigator track can satisfy the requirements for internal medicine and a subspecialty in the same period of time required for individuals who pursue a clinical training program.

The integration of the proposed research training structure with existing investigator track for clinical training is illustrated in Figure 4. Given the numerous possibilities for integrating clinical training requirements into a research training program and the likelihood of wide variation in individual preferences, the Task Force elected not to endorse any particular approach. Instead, the Task Force endorsed the concept of permitting individual training grant programs flexibility in accommodating the needs for clinical training.

However, the use of the training grant mechanism to support clinical training is unacceptable. It is apparent that postdoctoral positions on training grants are sometimes used to support individuals other than those committed to careers in biomedical research. As Dr. Wyngaarden stated in a November 15, 1984, letter to NRSA training directors,

“Since the goals of research training are clearly differentiated from the goals of clinical specialty training, the use of the training grant solely to meet specialty board requirements is a serious abuse of the mechanism. (Some specialty boards permit a year of research to count towards board eligibility. NRSA support for this period is warranted only if the trainee has shown clear interest in a research career.)”

The Task Force recognized that the NRSA training grant continues to be used inappropriately for clinical training by some training directors. As proposed earlier (Section B) in this report, improvements in

selection of trainees by training directors, loss of training positions and funds for positions filled by individuals who leave the program before completing their training, the revised review criteria, and modification of the payback provisions are expected to prevent this practice.

RECOMMENDATION

Multiple pathways should be permitted to accommodate the needs of individual trainees for specialty and subspecialty certification within the context of meeting the two-year required minimum research training experience.

D. New Approaches and Opportunities for Research Training

1. Programs in Epidemiology, Biostatistics, or Related Topics

The increased research focus on prevention of disease and on population-based studies requires expanded predoctoral and postdoctoral research training as well as research career development opportunities in the design, implementation, and analysis of various types of epidemiologic studies and clinical trials. (Clinical trials are defined as prospective evaluations of the diagnostic, preventive, or therapeutic effects of a drug, device, lifestyle, or procedure used or intended for use in the practice of medicine.)

The Task Force on Training Opportunities in Clinical and Community-Based Study Designs and Methodology developed a new approach for advanced programs in epidemiology, biostatistics, applied prevention research, or related topics. These programs, usually three to four years in duration, would include both didactic study and practical experience. Predoctoral training programs that lead to a Ph.D. or equivalent degree would be encouraged. Training will be based in institutions where the faculty is actively engaged in epidemiologic studies and clinical trials. Individuals who complete training would be capable of assuming leadership roles in the development and management of such studies.

Two additional types of programs for health professionals were identified by the Task Force to increase further the pool of research-oriented individuals available in these areas:

Master's degree-level programs of study in epidemiology, biostatistics, or related topics. Training would provide individuals opportunity to assume other important roles in epidemiologic studies and clinical trials. The didactic course work would be similar to that for advanced programs of study, but the practical experience provided would be less intensive.

Nondegree, certificate programs of approximately one-year duration (or equivalent) with an emphasis on epidemiology and biostatistics. At least 50 percent of an individual's effort would be in didactic course work. Rotation through epidemiologic

studies or clinical trials in different stages of development, observation in coordinating centers and other central study facilities, and extensive participation as an observer at clinical study meetings, such as Data and Safety Monitoring Committee meetings, would be included as practical training. Individuals completing such a program would be expected to participate more effectively in clinical studies.

Support for these programs would be provided through existing NRSA institutional and individual NRSA mechanisms as well as K-series awards developed for this purpose.

2. Predoctoral Individual Fellowships

The NIH abandoned the general programs of individual predoctoral fellowships when the NRSA was enacted because of the relatively large staff required for their review and administration and the difficulty of evaluating applicants so early in their careers. However, individual predoctoral fellowships currently are being used effectively by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), the National Center for Nursing Research, and the Minority Access to Research Careers (MARC) program.

The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists pointed out that awards under this mechanism can complement training grants. Such awards would allow access to predoctoral training support in institutions that are too small to justify a research training grant and in research areas that have not yet grown to a size that can support such training grants. Individual fellowships also allow students the greatest flexibility in choosing the training program best suited to them and in which they will feel most comfortable. The potential use of these fellowships to address specific NIH training needs should be reviewed.

3. Research Training in New Subject Areas

The establishment of new research training programs will vary according to the mission of each BID. The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists identified the need for NIH periodically to review training areas currently supported and to determine whether new areas need to be created or old areas eliminated. For example, there may be a need for more nonphysician researchers with training in human physiology and pathology. Therefore, a process should be put in place to evaluate the need for research training in underserved areas of biomedical and behavioral research as well as the need for new approaches in the use of existing mechanisms of support for training programs.

RECOMMENDATION

Advanced programs of study in epidemiology, biostatistics, or related topics should be supported to increase predoctoral and postdoctoral research training opportunities. K-series awards should be developed to expand research career development programs for these individuals.

Current NIH mechanisms also should be used to support master's degree- level programs of study in epidemiology, biostatistics, or related topics and nondegree certificate programs with an emphasis on epidemiology and biostatistics.

The opportunity for individual predoctoral fellowships to address specific NIH training needs should be reviewed.

An ongoing process should be instituted for evaluation of new research areas, approaches, and needs for NIH research training programs.

E. Trainee Stipends and Cost of Education

1. Trainee Stipends

Implementation of the new physician scientist research training concept will provide for training of individuals with a greater commitment to research. This is due to the minimum two-year requirement for research training, greater responsibilities on the part of the training directors and institutions, and more rigorous criteria for NIH review of new and competing renewals of training grant applications.

Fewer individuals may enter research training programs under the revised concept, but a greater percentage are expected to remain in research. The issue of whether stipend levels should be increased was discussed. An analysis of annual stipend levels for trainees was prepared and the current NRSA stipends and K-series award salaries as well as Association of American Medical Colleges (AAMC) data on housestaff salaries were examined. Stipend structures proposed by Task Force members and representatives of the scientific community were also considered. Concern was expressed that no increase in the stipend level is an important determinant in whether an individual remains on a training grant for a third year of training.

A proposed revision of trainee stipends was developed that would make trainee stipends comparable to current housestaff salary levels. It provides that individuals in the first postgraduate year (with zero years of experience) on a T award would receive a stipend of \$25,000, which is essentially equal to the average salary for the first postgraduate (intern) year. Additionally, the structure assures that an individual is never required to accept a reduction in remuneration to pursue research training. The proposal, along with data on existing NRSA stipends and

K-series award salaries, is shown in Table 1 and Figure 5. Examples of how training stipends would be integrated with clinical salaries are presented in Figure 6.

The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists also recognized the need to increase both predoctoral and postdoctoral stipends. Its members emphasized that the agencies that support research training in the biomedical sciences, i.e., NIH, ADAMHA, and the National Science Foundation (NSF) should explore means of making the support mechanism more equivalent in terms of stipend levels, cost of education, and other trainee expenses.

2. Cost of Education

The general findings of relevant earlier reports of the NIH Committee on Payment of Tuition for Research Training Grants and the Subcommittee on Training Stipends of the Extramural Program Management Committee (EPMC) were reaffirmed by the Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists. The institutional research training grant programs continue to play a crucial role in graduate education and in the research training of biomedical scientists. It is appropriate that the budgets for these awards include some support for the cost of education. However, it should be noted that, as grants-in-aid, these NIH awards are not obliged to pay full costs. The past two decades have seen constantly rising tuition charges, a declining NIH research training budget in real dollars (except for occasional stipend increases), and, consequently, sharp reductions in the number of predoctoral trainees supported. Many of the NIH Institutes

Table 1
Trainee Annual Stipend Levels

Current NRSA Stipends & K-Award Salary Levels

T Award	8,500							
Predoctoral								
Postdoctoral								
Years of Experience*	0	1	2	3	4	5	6	7
	17,000	18,000	25,000	26,250	27,500	28,750	30,000	31,500
K Award	≤ 40,000							

Mean Housestaff Salaries: AAMC Data

Postgraduate Years**	PG 1	PG 2	PG 3	PG 4	PG 5	PG 6
1988 - 1989 Salaries	23,382	24,813	26,141	27,421	28,699	30,129
1989 - 1990 Salaries	24,288	25,792	27,189	28,537	29,861	31,128

Proposed NRSA Stipends & K-Award Salary Levels

T Award	10,000								
Predoctoral									
Postdoctoral									
Years of Experience*	0	1	2	3	4	5	6	7	8
	25,000	26,500	28,000	29,500	31,000	32,500	34,000	35,500	37,000
K Award	≤ 50,000								

- * An individual with zero years of experience is in the first postgraduate year.
- ** An individual in the first postgraduate year has zero years of experience.

Figure 5
Housestaff Salaries and
Research Training Stipends

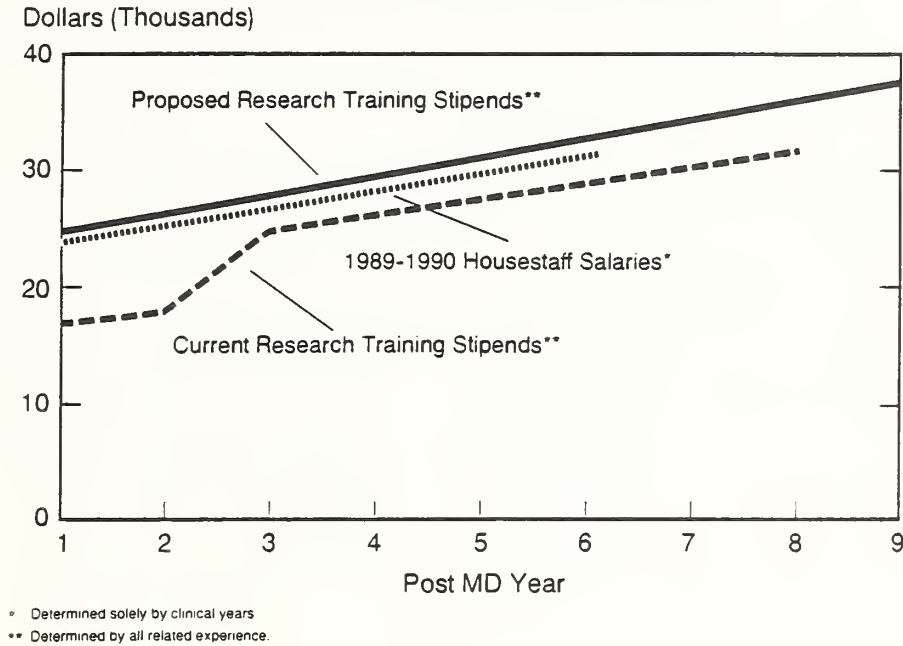


Figure 6a
Clinical Salaries and Research Stipends
Track I -- Two Year Option & Current
ABIM Investigator Track Requirements

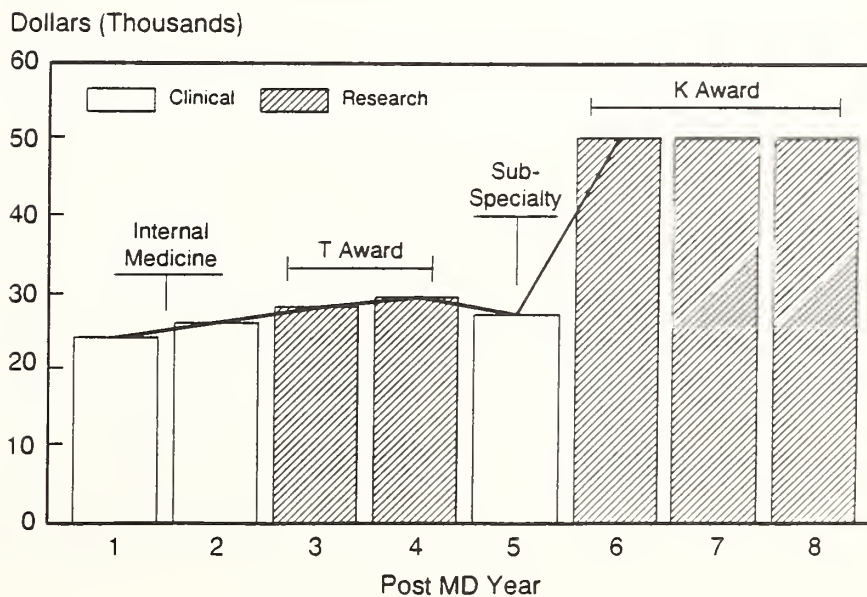


Figure 6b

**Clinical Salaries and Research Stipends
Track II -- Three Year Option & Current
ABIM Investigator Track Requirements**

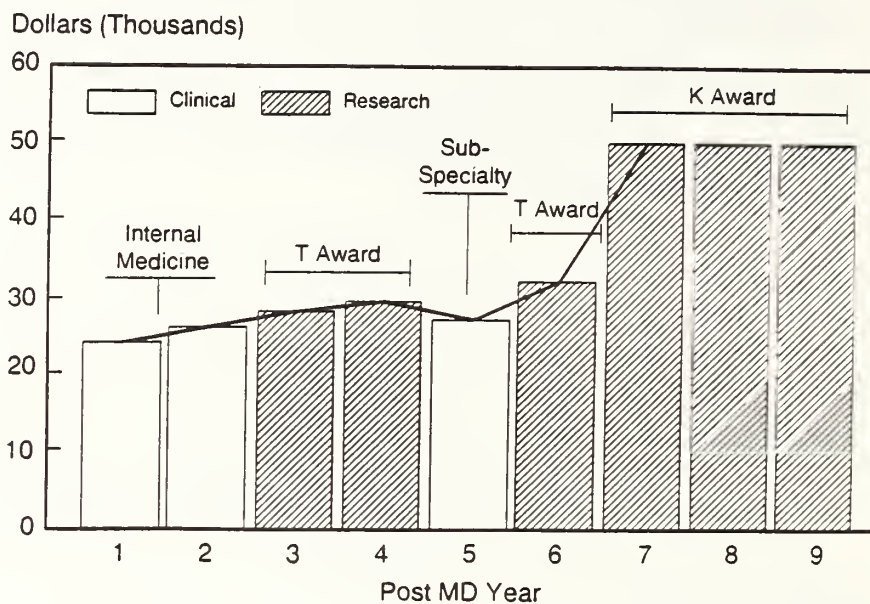
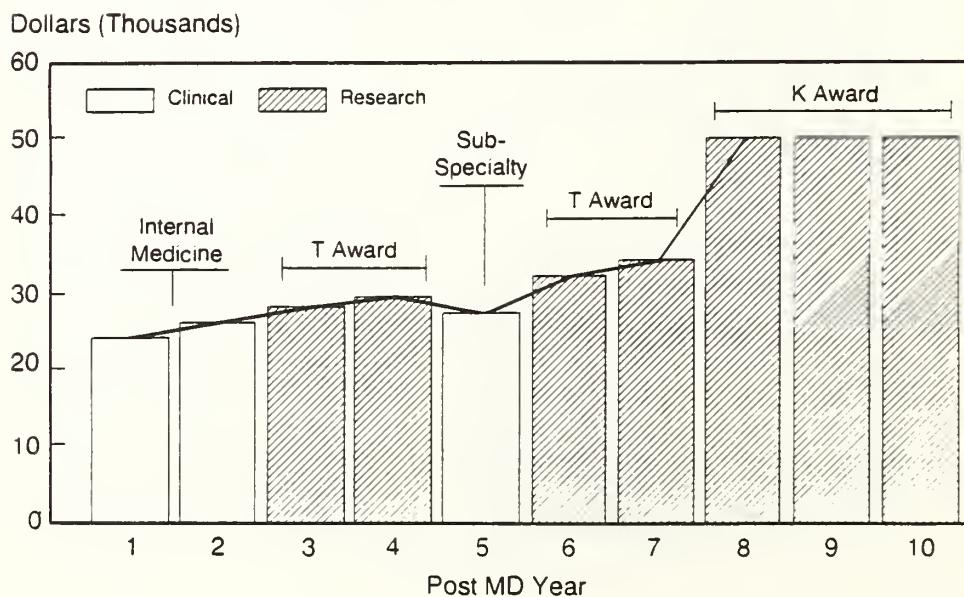


Figure 6c

**Clinical Salaries and Research Stipends
Track III -- Four Year Option & Current
ABIM Investigator Track Requirements**



periodically have frozen allowances for tuition to prevent an even greater decrease in the number of trainees.

The NIH Committee on Payment of Tuition for Research Training Grants proposed that NIH adopt a “two-tier cost of education (CoE) allowance” as a mechanism to control the fraction of the training budget designated for the CoE. It was reaffirmed that this mechanism seems to be the most practical and provides one CoE for predoctoral trainees at public institutions and another for those at private institutions.

Several other issues need to be taken into consideration in setting the yearly CoE allowance, the most important being the maintenance of *at least* a constant number of NIH-supported trainees. Annual increases in the research training budget would be requested in order to permit appropriate increases in the CoE allowance. Furthermore, although tuition is usually paid only for postdoctoral trainees who are enrolled in degree-granting programs, tuition payments for approved courses can be provided on a case-by-case basis. However, such payments should not exceed the predoctoral CoE allowance.

RECOMMENDATION

Levels of postdoctoral trainee stipends for professional doctorates should be increased to make them at least as attractive as current housestaff salaries. Levels of trainee stipends for predoctoral and postdoctoral nonphysician scientists should be increased each year, as needed, to compensate for the increase in the cost of living.

Those agencies of the Federal Government that support biomedical research training should explore ways of making the mechanism of support more equivalent in terms of stipend levels, cost of education, and other trainee expenses.

The proposal for NIH to adopt the “two-tier cost of education allowance” as a mechanism to limit tuition payments is reaffirmed. The CoE allowance for special NIH research training programs, such as the Medical Scientist Training Program (MSTP), should follow the same general principles.

F. K-Series Awards

Consistent with the overall five-year training concept, it was recognized that, after the minimum two-year research training experience on a training grant, a trainee would have the option to apply for an individual fellowship grant (F32), K-series award, FIRST award (R29), or a research project grant (R01) as illustrated in Figure 4.

The need was identified to modify the K-series awards to permit less than the current five-year duration. It was agreed that individuals may not need five more years for career development after completing the

minimum two years on a training grant. Therefore, a three-year award should be made available.

Summaries of several NIH K-series awards were reviewed. Presently, the NINDS offers the option of a three- or five-year K-series award, i.e., Clinical Investigator Development Award (K08).

The Task Force on Physician Scientist Training believes that three-year K-series awards are an important part of the revised training concept for physician scientists. It also believes that the salary support on an award received through a national competition (e.g., K-series award) after one or two years on a training grant should be higher, thus providing an incentive to compete for such an award. Salary levels for K-series awards were considered and members agreed that they should be integrated progressively with the stipend levels recommended for trainees on training grants (Table 1 and Figure 6).

RECOMMENDATION

Three-year K-series awards should be made available NIH-wide for professional doctorates. Salary levels for these awards should be increased to \$50,000 annually.

G. Data Collection, Monitoring, and Evaluation

1. Data Analysis

The success of past and current training endeavors designed to provide scientists for biomedical research should be assessed. A large body of data exists that must be analyzed appropriately. Although the Committee on National Needs for Biomedical and Behavioral Research Personnel of the Institute of Medicine/National Academy of Sciences has collected and analyzed some of the data, particularly in regard to the overall opportunities for research training, more must be done. The Task Force on Predoctoral and Postdoctoral Training of Nonphysician Scientists emphasized the need for analysis of available data and for development of an ongoing process of data collection on all predoctoral and postdoctoral trainees and fellows, including the MSTP. This process is particularly important to the revised training program structure. Some of the items needed for evaluating programs are:

The numbers of Ph.D. and M.D. degree holders and predoctoral students supported each year. The numbers supported by institutional awards and individual awards should be recorded separately.

For each NRSA recipient, the length of NIH-supported research training, as well as additional training support mechanisms used by Federal agencies, the pharmaceutical industry, the Department of Veterans' Affairs, the Howard Hughes Medical Institute, and foundations.

The time lag between completion of research training and the subsequent submission of requests for research support.

The types of grant applications submitted.

The research grant application and award histories of former trainees and fellows in addition to information on their subsequent scholarly research pursuits.

2. New Databases

Because other data are necessary to evaluate research training activities in a meaningful way, each BID should work to develop and maintain its own database on training programs. Many items of importance appear in competing continuation applications. Of particular interest are the number of, and information regarding, underrepresented minorities and women:

Appointed to research training grants.

Supported by other research training and career development mechanisms and by the Minority Biomedical Research Support (MBRS) program.

3. Available Resources

The NIH has a number of resources available for analysis and assessment of the many aspects of research training. By using these resources more fully and continuously, collection of data can be greatly improved. Information is available in various files and documents including the payback file, the doctorate record file, the consolidated grant applicant file, and the trainee/fellow file.

It was recognized that a burden will be imposed on the NIH staff, collectively and at a programmatic level, by enhanced data monitoring and evaluation. In order to perform a careful analysis of the NIH research training programs, priorities will have to be set regarding the importance of each of these data files and how much information can and should be collected. It must be stated, however, that such data are essential if a thorough and critical analysis and evaluation of research training programs is to be performed. Evaluation funds should be considered for these studies.

RECOMMENDATION

A continuing process of data collection should be developed to capture information about all predoctoral and postdoctoral research trainees and fellows, including MSTP students, and their subsequent scholarly research accomplishments. A set of standards for data collection should be developed to ensure that information is uniformly recorded and can be compared across NIH. The need for new databases should be an important ongoing consideration in this process.

Available NIH training data should be analyzed further. The NIH should provide support, either directly or through contractual arrangements, to capture data from existing NIH files into a central file so that the information is readily available for evaluation studies. It is further recommended that consideration be given to using the one percent set-aside evaluation funds for these tasks.

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